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Via eCourts
Honorable Judge Lougy, P.J.Ch.
Superior Court, Mercer County
Civil Courthouse
175 S. Broad Street, 3rd Floor
Trenton, New Jersey 08650

RE: Judith Persichilli v. Atilis Gym Bellmawr
MER-C-48-20

Dear Judge Lougy,

As this Court is aware, this Office represents Defendant Atilis Gym ("Atilis" or "Defendant"). Please accept this letter brief in lieu of a more formal brief in opposition to Plaintiff's December 10, 2020 motion to enter judgement against Defendant.

Material Facts and Procedural History

While Defendant does not wish to bemoan the procedural history, it is necessary given the gravity of the Constitutional liberties put in jeopardy. On March 9, 2020, Governor Murphy issued Executive Order 103 declaring a State of Emergency. This Order has been continuously renewed and modified by Governor Murphy. The Governor established a criteria for businesses

that were essential, and businesses they deemed to be not essential.[1] By March 21, 2020, Governor Murphy unilaterally closed any businesses it deems not to be "essential." Those of which he felt were non-essential were gyms. What was initially billed as temporary measures to flatten the curve and to protect hospital capacity has become open-ended with ongoing restrictions aimed at a different end; that is stopping the spread of the infectious disease and preventing new cases from arising. Even though the harshest measures have been suspended, through the Governor's public statements, these measures have only been suspended. The State of New Jersey admits that they remain in place and can be reinstated *sua sponte* as when the State sees fit. In other words, while not currently being enforced, New Jersey citizens, like Atilis, remains subject to the imposition of the most severe provisions at any time. The stated reason was to protect the health, safety and welfare of the citizens of New Jersey, for the goal of flattening the curve. The modified orders (TKTK THE PERCENTAGES CHANGE), one of which is the reason for the State trying to assert a penalty through this Court, have been issued without any scientific evidence. These percentage changes through the modified orders, without scientific evidence, are nothing more than a government actor own mental whim, intuition, or dictatorial instincts.[2] Furthermore, the government has shown that after a year there is no plan in place to return to the situation where there are no restrictions imposed.

[1] The State of New Jersey has never published any of its findings on how essential vs. non-essential businesses were determined.

[2] On or about April 20, 2020, Governor Murphy stated on national television that protecting constitutional liberties was "…above my pay grade." https://thehill.com/homenews/media/493109-foxs-tucker-carson-presses-nj-governor-on-whether-restrictions-violate-bill-of

On May 19, 2020, after 59 days of the Governor's unilateral decision, Defendant re-opened its doors to its members.[3]

On May 19, a political rally was held at Defendant's place of business to protest the government's non-scientific approach to the pandemic. Days later, on May 22, 2020, Plaintiff filed a verified complaint and order to show cause. On July 1, 2020 Plaintiff issued an Order to Defendant allowing them to reopen with certain restrictions. On July 20, 2020, this Court enforced that Order pursuant to R. 1:10-3. On August 18, 2020, this Court enforced its earlier order requiring Defendant to close its business and earn a living. On October 8, 2020, the Court amended its August 18, 2020 Order to reflect Commissioner Persichilli's August 28, 2020 Order. Both of these orders purportedly require Defendant to comply with all restrictions that Governor Murphy and Plaintiff set forth. Furthermore, any violation of such action would result in a fine of $15,497.76.

On December 8, 2020, Atilis Gym filed a motion asking this court to reconsider its November 18, 2020 Order as well as requesting the Court to vacate portions of its August 18, 2020 and October 8, 2020 Orders. Two days later, Plaintiff filed the instant motion seeking additional fines which would result in bankrupting Defendant as well as the individual owners in their personal capacities.

Plaintiff seeks to penalize Defendant for numerous images and videos posted on the internet without authentication. Plaintiff alleged that over the Course of 8 days in November that Defendant, gym visitors, and a national fitness Instagram page posted content which

[3] Atilis Gym now operates with volunteers working on a day-to-day basis as private membership association, therefore it currently has no paid staff-members. Atilis Gym's members also do not pay dues.

violated Governor Murphy and Plaintiff's unilateral orders. These violations consist of 10 alleged instances of no social distancing, 9 alleged instances of no barriers, 12 alleged instances of no masks being worn, 9 alleged instances of no demarcations being marked, and two instances of more than 60 occupants being present in the building.

These orders are not constitutional because they are arbitrary and capricious because there is no basis in scientific fact to support these orders and the delegation by the legislature of their legislative authority to the executive branch is violation of the separation of powers provision of the New Jersey Constitution.

Discussion

The COVID-19 pandemic has impacted every aspect of American life. Since the novel coronavirus emerged in late 2019, governments throughout the world have grappled with how they can intervene in a manner that is effective to protect citizens from getting sick and, specifically, how they can protect their healthcare systems from being overwhelmed by an onslaught of cases, hindering their ability to treat patients suffering from COVID-19 or any other emergency condition. In this country and state, founded on a tradition of liberty enshrined in our constitutions, this country and the governor of this state, notwithstanding his statement to the contrary (FN), as well as the courts, have grappled with how to balance legitimate authority of public officials in a health emergency with the rights of citizens.

The safeguard of the citizens of New Jersey's liberty is embedded in the actual structure of both the New Jersey Constitution and the United States Constitution. Specifically, it is found in the notion of the separation of powers doctrine articulated in Article III of the New Jersey Constitution. One of the purposes of the separation of powers is to prevent citizens through our

elected representatives from relinquishing those liberties, even in or for a state of emergency. It is without doubt that the separation of powers doctrine is designed to protect from one person rule. Absent a robust system of checks and balances the guarantees of liberty set forth in both constitutions are just ink on parchment or paper. As the United States Supreme Court has noted, "The Constitution was adopted in a period of grave emergency. It grants of power to the federal government and its limitations of the power of the states were determined in the light of emergency and are not to be altered by emergency." Home Building & Loan Association v. Balaisdell, 290 U.S. 398, 425 (1934).

The legislative scheme that has been adopted by the New Jersey legislature and relied on by government officials to enforce the current emergency health measures violate this basic constitutional principle.

The legislature's intent in passing the New Jersey Civilian Defense and Disaster Control Act is clearly set forth in N.J.S.A. App. A:9-33. This section reads,

> The purpose of this act is to provide for the health, safety and welfare of the people of the State of New Jersey and to aid in the prevention of damage to and the destruction of property during any emergency as herein defined by prescribing a course of conduct for the civilian population of this State during such emergency and by centralizing control of all civilian activities having to do with such emergency under the Governor and for that purpose to give to the Governor control over such resources of the State Government and of each and every political subdivision thereof **as may be necessary** to cope with any condition that shall arise out of such emergency and to **invest the Governor with all other power convenient or necessary to effectuate such purpose.** Id.

There are two questions presented to this court. First, whether or not executive branch's orders are arbitrary and capricious. They are. Secondly, whether or not the delegation by the

legislature of their legislative powers to the executive branch under the Disaster Control Act and Emergency Health Powers Act, violates the New Jersey Constitution and the United States Constitution. If the answer is yes, this Court has no authority to enforce the executive actions taken by Plaintiff and Governor Murphy, regardless of what stage the matter is in litigation, including enforcements of fines for contempt of court. The Committee To Recall Robert Menendez v. Nina Mitchell Wells, 204 N.J. 79 (2010).

The Governor of the State of New Jersey's Emergency Powers were borne out the state legislature's passage of N.J.S.A. App. A:9-33 et seq. In addition to the Governor's direct authority, executive authority is also granted to Plaintiff Persichilli through the Emergency Health Powers Act. N.J.S.A. 26:13 et seq. This statute recognizes that the Department of Health is an extension of executive authority.

Argument

A. The New Jersey Constitution Does Not Allow Judgement to Be Entered

The New Jersey Supreme Court in Brown v. Heymann noted that, "the doctrine of the separation of powers is designed to prevent a single branch from claiming or receiving inordinate power…" 62 N.J. 1 (1972). The nondelegation doctrine forbids the powers vested in one branch from being delegated to another. While the United States Constitution recognizes this important **implied** principle, the New Jersey Constitution **explicitly** does not permit such delegations. "The powers of the government shall be divided among three distinct branches, the legislative, executive, and judicial. No person or persons belonging to or constituting one branch shall exercise any of the powers properly belonging to either of the others, except as expressly provided in this Constitution." New Jersey Const. Art. III (Emphasis added). "The separation of

powers questions can arise when a branch delegates some of its own power away, or when a branch takes onto itself some of the powers of another branch." Communications Workers of Am. v. Florio, 130 N.J. 439 (1992). Despite the explicit constitutional mandate, the Supreme Court of New Jersey in *Communications Workers v. Florio* noted, "We have always recognized that the doctrine requires not an absolute division of power, but a cooperate accommodation among the three branches of government." Id. *citing* Brown v. Heymann, supra; General Assembly v. Byrne, 90 N.J. 376, 382 (1982); Knight v. Margate, supra, 86 N.J. at 388, 431.

In one of the first cases to address the separation of powers doctrine under the 1947 State Constitution, Chief Justice Vanderbilt's dicta noted that the inflexible classification of the branches of government cannot be, "mutually exclusive watertight compartments [that] would render government unworkable." *Communications Workers v. Florio, supra; Massett Building Co. v. Bennett,* 4 N.J. 53, 57 (1950). Although this is nothing more than dicta, it has been quoted in subsequent cases dealing with the separation of powers. See In re Salaries for Probation Officers, 58 N.J. 422, 425 (1971). It is important to note that this opinion is contrary to the purpose and design of the separation of powers doctrine. When the New Jersey constitution was adopted in 1947 there was no mention that the purpose of the new constitution was to make government workable.

The Governor's Executive Orders and the Commissioner's authority, the underlining subject matter in this enforcement proceeding, derives from the New Jersey Civilian Defense and Disaster Control Act N.J.S.A. App.A:9-33 et seq, and the Emergency Health Powers Act, §26:13-1 et seq. The challenge here, is not directed at the constitutionality of the Executive Orders, rather, defendant Atilis Gym is challenging the delegation of power from the legislative branch to the

Executive branch that these two statutes allow for. If the statutes are found to be an improper delegation of power, then the Executive Orders fail as a consequence. The Executive Branch's actions are being challenged because the actions taken are arbitrary and capricious.

It is well settled law in New Jersey that adopted legislation is presumed constitutional. [cite omitted]. The Courts are also to give the widest possible interpretation of the actions taken by an Executive in a time of emergency. Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579, 637 (1952). That deference does not prohibit a challenge to the statues in this case due to the extended time of the emergency and the relatively non-scientific basis the underlying orders are based on.

In the matter concerning the Disaster Control Act and the Emergency Health Powers Act, it is unequivocal that the governor is acting as both the chief executive and the legislature. In Worthington v. Fauver, this state's Supreme Court stated, "where the executive acts pursuant to an express or implied authorization from the legislature… he exercises not only his own powers, but those of the legislature." 88 N.J. 183, 208 (1982). Importantly, the *Worthington* court state:

> These powers under the statute represent an extraordinary delegation of authority by the legislature to the executive. Because of the extraordinary nature of that authority, the executive orders must not only bear a rational relationship to the goal of protecting the public, but their scope must not exceed the extent of the emergency. The statutory validity of the executive actions pursuant to emergency power will depend on the nature of the emergency and the gravity of the threat to the public. Thus, a more serious emergency may justify grater responsive measures.

There is no question that at the beginning of this emergency that our government took, what they believe, were necessary steps to protect the public and the resources of this state.

This was achieved through the closure of businesses, stratifying businesses into two groups (essential and non-essential), stay at home orders, and other measures that clearly involved legislative action and de facto suspension of liberties. In other words, the scope of these orders appears to fit the extent of the emergency. The same cannot be said from September of 2020 – present. The time period is important because The *Worthington* court also found that the Disaster Control Act does not permit any delegation of power to the executive to take permanent action. Id. Therefore, to properly analyze government action, it must be put into context. First by acknowledging that the executive branch's initial reaction to a novel virus may have been proper given the magnitude of the threat. The governor's actions, however, have taken root and have perpetuated for well over a year. It is within that context that the legislative delegation of power to executive branch is now violative of the separation of powers doctrine.

The *Worthington* Court established the standard of review to determine whether or not government action violates Article III of the State Constitution. That is the court must determine whether the conduct taken by an administrative or executive agency acted in an arbitrary and capricious manner. In essence, it is a rational basis test. The executive branch's orders must be rationally related to the magnitude of the threat of COVID-19. As noted herein, the executive branch's initial response is not at issue. It is the executive branch's response within the window of six months after the original declaration of emergency to present that is in question.

The *Worthington* court established that acting pursuant to the Disaster Control Act, the governor is empowered to make such orders, rules and regulations as may be necessary, adequately, meet the various problems presented by any emergency, and from time to time to amend or rescind such orders, rules and regulations, on any matter that may be necessary to

protect the health, safety, and welfare of the people or that will aid in the prevention or loss to the destruction of property. Id. at 193. Arbitrary and capricious means willful and unreasoning action without consideration and in disregard to the circumstances. Id.

I. The Governor's Executive Orders Were A Willful and Unreasoned in Light of The Current Circumstances. The Relationship Between the Current Orders and Magnitude of The Threat are Not Based on Any Scientific Proof or Effective Public Policy Measures And Therefore Are Arbitrary and Capricious

In the case at bar, the actions taken by the governor and Plaintiff do not adequately address the problems presented by the novel COVID-19 pandemic at this time. Although the governor has amended his numerous executive orders, he has not terminated his prior orders, he has merely suspended them. See Executive Orders. At the outset of this pandemic the governor articulated that he was following the guidelines of the CDC. On April 2, 2020 the Centers for Medicare and Medicaid Services (CMS) in consultation with the Centers for Disease Control and Prevention (CDC) issued critical recommendations to state and local governments as well as nursing homes to help mitigate the spread of COVID-19. These recommendations were based on longstanding infection control procedures. Specifically, the White House urged nursing homes to work with state and local leaders or units within a facility, to separate COVID-19 negative residents from the positive residents. An example was provided in the recommendations. That is, in Wilmington Massachusetts a single nursing facility with a 142-person capacity was designated a sole COVID-19 positive facility. See Exhibit A. Other nursing home residents who were positive for COVID-19 were moved from their prior residence to this dedicated COVID-19 Wilmington Massachusetts facility. This isolated and separated the COVID-19 positive residents from the COVID-19 negative residents and placed them into a separate facility. Plaintiff and Governor Murphy took a different approach. Instead of designating separate

facilities like they did in Wilmington Massachusetts, they ordered the return of COVID-19 positive residents back into the general population of nursing homes where they originally came from upon release from the hospital. Despite the ability to takeover healthcare facilities under the Emergency Health Powers Act, no effort was made by Plaintiff or the governor to establish COVID-19 only nursing home facilities. They deemed it sufficient just to separate residents within the facility which contained healthy residents, who later became infected.[4]

On March 21, 2020, the governor issued Executive Order No. 107 directing all residents to remain home until further notice. This same executive order also closed businesses across the state which were unilaterally deemed not essential. The governor, in his many news conferences, repeatedly stated that he was following the science. The CDC, however, never recommended draconian stay at home measures to require healthy people to stay at home, or to place sick senior citizen residents in general population with healthy senior citizen residents. This type of lockdown is unknown and untried in response to any previous pandemic or epidemic in human history. Business closures and lockdowns are not even mentioned in recent guidance offered by the CDC.[5] Exhibit B. These guidelines offer to help state, tribal, local, and territorial health departments with pandemic planning and decision making by providing updated recommendations on the use of non-pharmaceutical interventions. It presents an array of personal protective measures (i.e., staying home **when sick**, hand hygiene, and routine cleaning) and community level non-pharmaceutical interventions that may be taken by state and local

[4] "Remember, these are the folks' residences. Judy [Persichilli] reminded us of that in early April of last year. This is not like we were taking people out of hospitals to try to find a place for them that had no connection or there was abstract. These are their residences, this is where they live." *TRANSCRIPT: March 22nd, 2021 Coronavirus Briefing Media* https://nj.gov/governor/news/news/562021/approved/20210322c.shtml

[5] Community mitigation guidelines to prevent pandemic influenza - United States 2017.

authorities. The community level interventions include temporary school closures and dismissals, social distancing in workplaces and the community, and cancelling of mass gatherings. There are no recommendations in the document that even approximate the imposition of statewide (or even community-wide) stay at home orders or the closure of all non-essential businesses. Even for a pandemic that is rated "very high severity" the guidelines provide only that the CDC recommends **voluntary** home isolation of **ill persons**. The CDC might recommend voluntary home quarantine of exposed household members in the areas where the novel influenza circulates. This is a far cry from the statewide lockdown and the closing of non-essential businesses and limiting their capacities The fact is the lockdowns, and the closure of non-essential businesses is unprecedented in our history and has no basis in scientific fact.

Dr. Jayanta Bhattacharya, a professor at Stanford University, filed a declaration in the case *Il Bacco Restaurant Corp, et al v. Andrew Cuomo, et al.* Dr. Bhattacharya is the director of the Stanford Center of Demography and Economics of Health in Aging. His focus is on epidemiology and infectious disease epidemiology. Dr. Bhattacharya affirmed that lockdowns are harmful. See Exhibit C, ¶17. He articulated essentially the same recommendations that was offered by the CDC in preventing the spread of the flu virus in a pandemic. He stated, "…The most compassionate approach to the COVID-19 pandemic is one that allows those who are at minimal risk to live their lives normally to avoid lockdown harms while better protecting those who are at highest risk from COVID-19 infection." Id. He referenced a document named *The Declaration*, known as the Great Barrington Declaration.[6] The declaration was written from a global public health and humanitarian perspective. The declaration was co-signed by more than 12,000

[6] https://gbdeclaration.org

medical and health scientists and 35,000 medical practitioners. In his declaration for the *Il Bacco* matter, he noted that according to epidemiological data 74% of the COVID-19 spread in New York are from private gatherings. He states, "I am unaware of any evidence to suggest that indoor dining is more likely to result in the spread of COVID-19 than is permitted in such venues such as casinos, bowling alleys, museums, Target stores, and Walmart..." Id. at ¶25. Here, Dr. Bhattacharya clearly establishes that there is no epidemiological support to close non-essential businesses. The evidence shows to the contrary that most of the spread takes place by residents in private gatherings. To date, the State of New Jersey has not offered or published any scientific data to support lockdowns and the restrictions placed on businesses. Dr. Bhattacharya declaration is consistent with previous public health measures taken in prior pandemics. Lockdowns and business restrictions are out of the (pre covid-19) mainstream of scientific evidence or thought in dealing with pandemics. Lockdowns are, therefore, truly unprecedented from a legal perspective and untried from a scientific perspective. Indeed, scientific research has clearly demonstrated that the lockdowns and even social distancing measures and the wearing of surgical or cloth masks are not effective non-pharmaceutical measures to protect from the COVID-19 virus.

In a study published in November by the New England Journal of Medicine from researchers from the ICAHN School of Medicine at Mount Sinai Hospital and the Naval Medical Research Center demonstrated that despite strict quarantine measures, COVID-19 spread amongst the United States Marine Corps. recruits. Exhibit D. The authors stated that the findings show that the transmission occurred despite the use of many infection control best practices. The study allowed for 1,848 participants who were quarantined and tested prior to entering the

military campus. They were tested after a 7-day period and a 14-day period. 1,554 Marine recruits did not participate in the study but maintained quarantine and had testing available to them. The results between the two groups show no statistical difference in the rate of infection between the two groups.

In May 2020 the CDC published a policy review for non-pharmaceutical measures for pandemic influenza in non-healthcare settings-personal protective and environmental measures. The policy reviewed the evidence based on the effectiveness of non-pharmaceutical personal protective measures and environmental hygiene measures in non-healthcare settings. The review found that evidence from 14 randomized controlled trials showed these measures did not support a substantial effect on transmission of laboratory confirmed influenza. Specifically, they did not find any evidence that surgical face masks were effective in reducing laboratory confirmed influenza, either when worn by infected persons, or by persons in the general community to reduce their susceptibility. They note that facemasks might be able to reduce of other infections but have no factual support to support that statement. See Exhibit E. This is not surprising and consistent with other previous findings by the CDC.

The World Health Organization in February 2019, published under the rubric *Global Influenza Program* a report of systematic literature reviews, non-pharmaceutical public health measures for mitigating the risks and impact of epidemic and pandemic influenza. The scope of the review includes evidence on the effectiveness of interventions such as personal protective measures, including environmental measures, social distancing, and wearing masks. The executive summary states “There is limited evidence based on the effectiveness of non-pharmaceutical community mitigation measures. There are a number of high quality randomized

controlled trials demonstrating that personal measures (e.g. hand hygiene and face masks) have it best a small effect on transmission, with the caveat that higher compliance in a severe pandemic might approve efficacy." See Exhibit F. Moreover, the study found that clothing such as scarfs or rags have no evidence of effectiveness because there is insufficient information available on their effectiveness. Surgical masks **may** only help block large particle droplets, splashes, sprays, or splatter, but they are not designed to protect against breathing in small particle aerosols that may contain viruses such as COVID-19. The study did demonstrate, however, that the use of respirator masks also known as N95 proved effective for blocking. The final and most important point of this study demonstrates that there was no significant risk reduction against a person being infected by the flu.

The CDC in 2009 published a research paper *Facemasks Use and Control of Respiratory Virus Transmission in Households.* Exhibit G. With essentially the same findings that there are no statistical support regarding the efficacy of surgical and cloth masks. The Study's focus was to prevent the spread of influenza during a pandemic by using non-pharmaceutical interventions, masks.[7]

As of today, there is now strong scientific evidence that social distancing (six feet apart) in indoor facilities is non efficacious. Nor is there any evidence that operating businesses at reduced capacity has any effect as well. In a study published on April 27, 2021 by the Proceedings of the National Academy of Science of the United States of America, one of the two authors,

[7] Prior to the current pandemic, the world was gearing up for another flu pandemic. Most studies relating to public health measures to prevent another pandemic focused on non-pharmaceutical mitigation measures for the flu. The flu virus transmission and symptoms are similar. They both spread via person-to-person in close contact, mainly by aerosol droplets. COVID-19, however, is more contagious than the fly. See Exhibit H.

Professor Martin Bazant from the Massachusetts Institute of Technology stated, "the distance (six feet away) isn't helping you that much and it is also giving you a false sense of security, because you are as safe at six feet as you are at sixty feet, if you are indoors. Everyone in that space is at roughly the same risk, actually." He further stated, "What our analysis continues to show is that many spaces that have been shut down, in fact do not need to be. This study has undergone three rounds of peer review. Oftentimes, the space is large enough and the ventilation is good enough, the amount of time people spend together is such that those spaced can be safely operated even at full capacity, and the scientific support for reduced capacity, is really not very good." Exhibit I.

In essence, as stated herein, the actions taken by the governor and Plaintiff do not adequately address the problems presented by the novel COVID-19 pandemic at this time. The current orders are not rationally related to his goal of preventing the spread of COVID-19 based upon the scientific evidence demonstrated herein. His stated initial goal of preventing the spread was to flatten the curve and to protect our healthcare resources. There is no evidence that there is any current threat to these resources because the curve has been flattened since last June.

The governor's policies are willful and unreasoned without consideration and in disregard to the circumstances because there was never any CDC recommendation to close businesses or open them limiting their capacity in the first place. This policy choice was an executive decision by him and him only without any basis of support, scientific evidence and is without any prior history demonstrating that lockdowns and limits on business capacity are effective measures. He also noted that he was not concerned with the Bill of Rights. Nor was there any scientific basis promulgated to support the division of essential and non-essential business. Again, this was

simply a measure taken by fiat. As such, Plaintiff nor the governor have acted with any scientific basis whatsoever for the lockdowns, the reduced capacity requirements, and other ordered mitigating measures including social distancing and mask wearing. Fear and concern for the public health alone is not enough of a reason to suspend constitutional norms. As such, his Orders from September 2020 up until now are arbitrary and capricious.

II. The New Jersey Civilian Defense and Disaster Control Act, and The Emergency Health Powers Act Are Violative of The Separation of Powers of New Jersey Constitution, Article III, and the Implied Separation Doctrine in the United States Constitution In This Case

The Worthington v. Fauver court articulated three areas of consideration in evaluating an executive order violates Article III of the New Jersey Constitution. Those factors are (1) whether the orders represent a usurpation of legislative power by the executive branch, (2) whether the enabling legislation represents an unconstitutional delegation of legislative power to the executive, and (3) whether the legislative delegation of power or the executive implementation of the orders impermissibly encroaches on the proper sphere of the judiciary. Worthington v. Fauver, 88 N.J. 183 (1982). Here, we do not have a usurpation of a legislative power by the executive branch as the legislature delegated all of their powers to the executive branch during a state of emergency. There is also no encroachment on the judiciary branch's authority to review the actions taken by a co-equal branch. We are left with the question, whether the enabling legislation represents an unconstitutional delegation of legislative power to the executive branch via the Civilian Defense and Disaster Control Act, and the Emergency Health Powers Act. See N.J.S.A. App.A:9-33 et seq; §26:13-1 et seq.

When the legislature delegates their powers they "may enact statutes setting forth in broad design its intended aims, leaving the detailed implementation of the policy thus expressed

to an administrative agency." Cammarata v. Essex Cty. Park Com., 26 N.J. 404, 410 (1958). The record of these two statutes, the Civilian Defense and Disaster Control Act and Emergency Health Powers Act, is devoid of any substantive legislative history regarding the stated policy goal. For analysis purposes, we are left with prior caselaw and prior public policy statements by the courts in those cases.

In *Worthington,* the State Supreme Court notes that the purpose of these statutes is to prevent damage from occurring during a disaster and to empower the executive branch to act and protect the health, safety, and resources of the residents of our State. The New Jersey Supreme Court noted, "In a situation of impending danger, it may be difficult to determine whether the legislature can be galvanized to act in time to prevent the disaster." Worthington v. Fauver, at 196. Embedded in this comment is the idea that time is a factor in allowing the delegation of legislative powers. In the instant case, the COVID-19 pandemic is currently well over a year old. During that time, the governor has issued modified orders while merely suspending, not terminating prior orders. The orders themselves therefore have no end date or expiration, leaving the public susceptible to open ended draconian measures. New Jersey courts have shown complete deference and a desire to not get involved between the two branches. The Court did emphasize, however, a responsibility of the branches of government to seek legislative answers to long term problems. The Court stated:

> We believe, however, that the Disaster Control Act does not permit any delegation of power to the executive to permanently authorize the action taken. Rather, it grants extraordinary power to the executive branch in time of emergency to protect the public. From this limited legislative purpose, we infer an obligation on the executive and legislative branches to seek legislative solutions to long

> term problems such as prison overcrowding. Worthington v. Fauver, at 203.

The *Worthington* court specifically did not rule on frequency of executive orders being renewed to extend emergencies or on the length of time which he can continue to exercise his authority. The court stated:

> We express no opinion as to how often the governor can renew Executive Order No. 106, or the length of time during which he can continue to exercise these extraordinary powers, before we would conclude that he had exceeded his authority. [cites omitted] Id. at 203-04.

Although judicial review on the exercise of delegated powers is limited, and the executives should be supported by the strongest presumptions and given the widest latitude of judicial interpretation. The New Jersey Supreme Court has left the door open as for a court to determine whether or not the scope of Plaintiff and the governor's actions over a long period of time can be reviewed in a challenge to the delegation doctrine. In the instant matter, as previously stated, the measures taken have been in effect for over a year with no discernable end in sight. In contrast to prior pandemics, this period of government emergency is an extraordinary amount of time.

During this period of time the executive branch has failed to recognize and acknowledge the new scientific information available to it. Instead, there has been a slow-walk of lifting arbitrary restrictions like capacity limits in facilities and in non-essential businesses. Needless to say, the economic impact on these businesses have been devastating. Particularly, the small businesses like Atilis Gym have been subjected to loss of economic liberties.

Based on the history of prior declarations of emergency, which have involved short durational time periods, it is impossible to argue that the legislature foresaw the draconian

measures that have taken place during this emergency would last so long. As such, it is necessary despite the deferential standard, that a court weigh in to determine whether or not this extraordinary time period of this emergency is warranted. In a recent Harvard Law Review article titled *Coronavirus, Civil Liberties, and the Courts: the case against suspending judicial review,* 133 Harv. L. Rev. F. 179 (2020), Lyndsay F. Wiley & Steven I. Pladack argued against overly deferential suspension by the courts in the time of an emergency. The article stated, "that the suspension principle is inextricably linked with the idea that a crisis is often finite and brief in duration. To that end, the principle is ill suited for long-term open-ended emergencies like the one which we currently find ourselves in." Id. The article also stated:

> …the most critical failure of the suspension model is that it does not account for the importance of an independent judiciary in a crisis. As perhaps, the only institution that is in any structural position to push back against potential overreaching by local, state, or any federal political branch. Id.

Since the New Jersey Supreme Court specifically left the door open to a temporal analysis regarding the delegation of legislative authority, there is no better case than this one of the courts to consider whether or not an extended time period of emergency qualifies for judicial review.

III. The Plaintiff's Orders Violate the Owners of Atilis Gym Right to Substantive Due Process Under the Fourteenth Amendment of the United States Constitution

The Governor's orders initially shut down all businesses that were deemed non-essential and allowed essential businesses to remain open. Although since suspended, new orders allowing non-essential businesses to open with limited capacity is still in effect. Additionally, since the orders are suspended, businesses like Atilis Gym are still subject to another shutdown. The public

record shows that Plaintiff and the governor have never had a set definition in writing of what constitutes an essential business. While the historic record shows that certain economic activities were curtailed in response to the Spanish Flu pandemic, there has never been an instant where a government or agent thereof has *sua sponte* divided every business in the State into two categories- essential and non-essential – and closed all businesses and limited their capacities to open. Admittedly, the unprecedented nature of the business closure, even in light of the emergency, makes a constitutional analysis difficult. It simply does not neatly fit with any precedent ever addressed by our courts. Never before has government exercised such vast and immediate power and control over every business owner and citizen in this State. More importantly, never before has the government taken direct action which shuttered so many businesses and sidelined so many employees and rendered their ability to operate and to work and to employ solely dependent upon government discretion.

a. The Challenges to the Business Closures and Limitations are Ripe for Review

The business closure orders provisions remain reviewable under the voluntary cessation doctrine. The closure orders were never rescinded. Rather, they are merely suspended and can be reinstated at any time.

i. **The Fourteenth Amendment Guarantees A Citizens Right to Support Himself By Pursuing A Chosen Occupation**

The right of citizens to support themselves by engaging in a chose occupation is deeply rooted in our nation's legal and cultural history and has long been recognized as a component of the liberties protected by the 14th Amendment. Truax v. Raich, 239 U.S. 33, 41 (1915). (Holding that a state anti-alien labor statute violated both equal protection and due process). The Supreme Court stated that, "It required no argument to show that the right to work for a living and the

common occupation of the community is of the very essence of the personal freedom and opportunity that was the purpose of the 14th Amendment to secure."

The third circuit has recognized, "The right to hold specific private employment and to choose a chosen profession free from unreasonable governmental interference comes within both the liberty and property concepts of the fifth and fourteenth amendment." Piecknick v. Commonwealth of Pennsylvania, 36 F. 3d. 1250, 1259 (3d. Circ. 1994) *citing* Green v. McElroy, 360 U.S. 474, 492. These precedents are not to be confused with the right to a specific job. It is the liberty to pursue a calling or occupation that is secured by the 14th amendment. Traux at 41.

Plaintiff and the Governor's orders have interfered with Atilis Gym's owners right to engage in the pursuit of his or her chosen profession free from government interference. McCool v. City of Philadelphia, 497 F. Supp. 2d. 307, 328 (2007). The Due Process Clause of the 14th amendment includes a substantive component that bars arbitrary wrongful government action, regardless of the fairness of the procedures used to implement them. Zinermon v. Burch, 494 U.S. 113, 125 (1990). In reviewing a substantive due process claim, the, "criteria to identify what is fatally arbitrary differ depending on whether it is legislation or a specific act of a government officer that is at issue." City of Sacramento v. Louis, 523 U.S. 833, 846 (1998). "Specific acts," are also known as executive acts in substantive due process analysis. The third circuit has explained that, "Executive acts such as employment decisions typically apply to one person or to a limited number of persons while legislative acts, generally laws and broad executive regulations apply to large segments of society." Nicholas v. Pennsylvania State University, 227 F. 3d. 133, 139 n.1 (3d. Cir. 2000). Here, the governor is acting as both an executive and the legislature. Substantive due process challenges to legislative acts are reviewed under the rational basis test. Am Express

Travel Related Services Inc. v. Sidamon-Eristoff, 669 F. 3d. 359, 336 (3d. Cir. 2012). The total shutdowns of businesses here in New Jersey with no end date and with the specter of additional future shutdowns has caused critical damage to Atilis Gym's ability to survive and to other employees' ability to support themselves. Although the initial shutdown was temporary, as noted, the orders are merely suspended. The loss to Atilis Gym may be permanent due to whatever temporary measure the government deems appropriate. The rational basis test requires only that the government action "bear a rational relationship to some legitimate end." Romer v. Evans, 517 U.S. 260, 631 (1996). Conversely, actions which are irrational, arbitrary or capricious do not bear a rational relationship to any end.

To date, the public record demonstrates that the executive branch made a unilateral decision as to which classes of business would be classified as essential businesses. There has never been any formalized document produced not has there been any specific definition promulgated. This can be defined as nothing more than shockingly arbitrary. A demonstration of how broad and arbitrary these decisions have been made is when the Department of Health allowed Defendant to open its doors for the limited purposes of selling vitamins, tee shirts, and other tangible items. In essence, they completely shut them down and then said, "By the way we did not know you had another business contained in your gym." Another nature of the arbitrariness of the government action is when big box stores like Walmart and Home Depot remained while smaller businesses were forced to remain closed. As such, the government's actions can be categorized only as arbitrary and capricious.

IV. Plaintiff and Governor Murphy's Actions Have Violated The Equal Protection Clause Of The 14th Amendment of the United States Constitution

The equal protection clause forbids states to, "deny a person within its jurisdiction the equal protection of the laws." U.S. Const. 14th Amendment. In the instant matter, this claim arises under the "class of one" theory. Village of Willowbrook v. Olech, 528 U.S. 552, 564 (2000). In order to prevail a defendant must show that he was treated differently than others in similarly situated, defendant did not do so intentionally, and there was no rational basis for the difference in treatment. Hill v. Borough of Kutztown, 455 F. 3d. 225, 239 (3d. Cir. 2006). As noted herein, Atilis Gym was treated different than other business similarly situated in the state as their apparel and vitamin shop were initially closed while big box stores selling the same products remained open. Moreover, Atilis was singled out within their community for repeated fines while a neighboring karate studio remained open. Additionally, there is ample video evidence to demonstrate that other gyms in the state remained open, and openly bragged about it, without any fines or closure orders. This clearly demonstrates and establishes that the distinction between Atilis and these other facilities was made intentionally. Again, the nature of the state discerning between essential and non-essential businesses, essentially single handedly pick which businesses could stay open and which businesses must close. While picking winners and losers, they had an obligation to do so based on objective definitions and measurable criteria. Finally, the public record demonstrates that the shutdown of non-essential businesses did not rationally relate to defendant's stated purposes. The public stated purpose of closing non-essential businesses was to limit personal interactions in order to limit the scale and scope of personal interactions and reduce the number of COVID-19 infections. This of course was all done while big box stores remained open allowing for large crowds, while smaller stores like Atilis Gym had to close. These distinctions were arbitrary in origin and in application. They violate the equal protection clause.

V. The Defendants Are Not in Violation of Lawful Orders

Plaintiff alleged that there have been instances in which videos or photos posted online showing 10 alleged instances of no social distancing, 9 alleged instances of no barriers, 12 alleged instances of no masks being worn, 9 alleged instances of no demarcations being marked, and two instances of more than 60 occupants being present in the building. Because of these alleged instances, Plaintiff now seeks to collect nearly $200,000.

The Fines are Not Coercive, rather, they are punitive which runs counter to the coercive goals of R. 1:10-3. Assessing such a fine would render Defendant bankrupt. This matter came before the Court via R. 4:67-6 which allows an agency to bring an action to enforce an agency order. Movant now seeks to have this Court's Order which was granted pursuant to R. 1:10-3 reviewed. This rule, also known as a motion, to enforce litigant's rights, is not to be used for punitive measures. The New Jersey Supreme Court has stated that, "The motion to enforce litigant's rights described in Rule 1:10-3 is addressed to a court's 'inherent right to invoke coercive measures designed to compel a recalcitrant party to comply with a court order.'" Manalapan Realty, Ltd. P'ship v. Twp. Comm., 140 N.J. 366, 392 (1995) citing S.S. v. E.S., 243 N.J. Super. 1, 8, 578 A.2d 381 (App.Div.1990) (emphasis added). This is supported by the State Supreme Court's more recent decision in Abbott ex rel. Abbott v. Burke, "The scope of relief in a motion in aid of litigants' rights is limited to remediation of the violation of a court order." 206 N.J. 332, 371 (2011). As discussed above, the Court Order subject to enforcement relied upon the unconstitutional acts taken by Plaintiff and Governor Murphy. A court is allowed to impose appropriate sanctions if it finds the non-compliant party was able to comply and cannot show

that the failure to do so was excusable. See Milne v. Goldenberg, 428 N.J. Super. 184, 198 (App. Div. 2012).

The courts in this State have taken up the difference between a R. 1:10-2 hearing (contempt) and a R. 1:10-3 hearing (enforce litigant's rights). "The proceeding under that rule [R. 1:10-2] is penal in nature. A defendant charged thereunder must be afforded all of the rights of one charged with a crime except the right to indictment and to trial by jury. This includes the right to have the order to show cause itself specify the acts or omissions alleged to have been contumacious. Moreover, the order to show cause must clearly indicate that it involves a true contempt proceeding and not, as here, supplementary relief to the litigant." Zoning Bd. of Adjustment v. Datchko, 142 N.J. Super. 501, 509-10 (App. Div. 1976). In the matter before this Court Defendant has not received any of the rights afforded to a person charged with a crime despite Defendant's actions resulting in criminal charges lodged against the owners of Defendant Atilis Gym. Accordingly, the matter before this Court is to decide if the penalty is coercive.

The purported reason that Plaintiff seeks to close Atilis Gym is to stop the spread of COVID-19. A fee of $15,497.76 for failure to comply with unconstituional Orders is punitive. Instead, it is meant to crumble Defendant in a financial manner, and force Defendant into bankruptcy. This strikes to the core of the decision in Milne v. Goldenberg where it was held a party is entitled to enforce their rights via R. 1:10-3 if, "the non-compliant party was able to comply with the order and unable to show the failure was excusable, it may impose appropriate sanctions." 428 N.J. Super. 184, 198 (App. Div. 2012). Movant now submits to this Court that Defendant's right to avoid bankruptcy is excusable.

Plaintiff alleges that there were not demarcations, however the Gym's floors do in fact have demarcations to caution others to social distance in high traffic areas. Moreover, Executive Order 181 ¶1(d) allows for persons to be near one another and using the same equipment if they were immediate family members, caretakers, household members, or romantic partners. Plaintiff should not be rewarded $15,497.76 for blanket accusations of violations. Plaintiff has no way of possible knowing if the persons in the videos were not in the groups as contemplated in this section of the executive order.

Upon viewing the video, it was incredibly difficult to assess if persons were not six feet apart without scale. Defendant submits that such proof would require a professional opinion and would need to show that persons that are not immediate family members, caretakers, household members, or romantic partners were within six feet of each other.

Notably drawing attention to Defendant is their insistence to not require masks. For the above-mentioned reasons, Defendant does not believe the orders requiring them have Constitutional teeth. Despite this controversial topic, science and Governor Murphy's Executive Order 181 agree on one thing: Masks should not be worn when they would "inhibit that individual's health…" See E.O. 181, ¶1(p). Masks are unhealthy and should not be worn when conducting aerobic exercises. It is unequivocally unhealthy and impractical to wear a mask when working out at Defendant's location because it would inhibit their health and increase their risk of contracting covid-19. To date, Plaintiff has not provided science indicating otherwise, and Defendant would gladly provide their anecdotal data in a proper notice and comment period as provided by N.J.S.A. 52:14B-1 et seq.

One video, "3_11.20.20_ video.mp4" was taken in February of 2019. Nonetheless, because it was posted during Plaintiff's unlawful lockdown – a fee of $15,497.76 is sought. Defendant submits that Plaintiff cannot properly meet its burden to sufficiently prove such violations have occurred.

Plaintiff additionally seeks fines due to their improper calculation of the stated maximum capacity as required by Executive Order 181 ¶1(a). Defendant submits that numerous persons in the video were volunteers and staff of Atilis, and should not be included in the total number.

In the instant matter before this Court there has been no such action in regard to the arbitrary and capricious closings of gyms and orders from the State. The State continues to seek steep fines to be levied against Defendant in the form of R. 1:10-3 in an attempt to force Defendant into complying with the unconstitutional actions.

Additionally, Defendant is exercising its constitutional right. "The people have the right freely to assemble together, to consult for the common good, to make known their opinions to their representatives, and to petition for redress of grievances." N.J. Const. Article I, ¶18. This provision of the New Jersey Constitution protects Defendant as they are openly protesting the unlawful actions of requiring businesses to close, implement draconian measures, and take away their ability to provide for their families. The actions taken place by Defendant is a protest and this is abundantly clear. There regulations and Orders implemented by Plaintiff and Governor Murphy do not serve a legitimate state interest and impede on Defendant exercise of expressional freedom. See State v. Schmid, 84 N.J. 535 (1980). It was found that "The First Amendment was designed by its framers to foster unfettered discussion and free dissemination of opinion dealing with matters of public interest and governmental affairs." Id at 542 (Citing

Mills v. Alabama, 384 U.S. 214, (1966); State v. Miller, 83 N.J. 402, 412 (1980). Schmid went on to state, "The guarantees of the First Amendment are effectuated against potential state interference through the Fourteenth Amendment by limiting the extent to which states can restrict individuals in the exercise of rights of speech and assembly." Id at 542-43.

Conclusion

Accordingly, Defendant asks the Court to DENY Plaintiff's motion to enter default for the reasons submitted above.

Respectfully Submitted,

/s/ Giancarlo Ghione
Giancarlo Ghione, Esq

Exhibit A

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Press release

Trump Administration Issues Key Recommendations to Nursing Homes, State and Local Governments

Apr 02, 2020 | Nursing facilities

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Today, at the direction of President Trump, the Centers for Medicare & Medicaid Services (CMS), in consultation with the Centers for Disease Control and Prevention (CDC), issued critical recommendations to state and local governments, as well as nursing homes, to help mitigate the spread of the 2019 Novel Coronavirus (COVID-19)

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in nursing homes. The recommendations build on and strengthen recent guidance from CMS and CDC related to effective implementation of longstanding infection control procedures.

Nursing homes (also known as "skilled nursing facilities" under the Medicare program and "nursing facilities" under Medicaid; or "long-term care facilities") have become an accelerator for the virus because residents, who are generally vulnerable to complications from the virus, are even more so in an enclosed environment like a nursing home. In one Maryland nursing home, COVID-19 cases grew from one confirmed case one day to 64 confirmed cases the next. Hundreds of facilities across the country are experiencing increased numbers of cases among residents. To address this spread, CMS, which inspects Medicare-participating facilities to ensure compliance with Federal safety rules, has worked hand-in-hand with CDC to provide nursing homes with clear guidance on how they can keep their residents safe. Most recently, on March 13, CMS issued guidance that advised nursing homes to restrict visitors, helping prevent introduction of the virus into these facilities.

Additionally, on March 23, CMS announced new, focused infection control surveys intended to assess facilities' compliance with infection control requirements to

COVID-19
Mar 23, 2020

CMS Administrator Seema Verma's Remarks as Prepared for Delivery: Updates on Healthcare Facility Inspections in light of COVID-19
Mar 23, 2020

CMS Sends Guidance to Programs of All-Inclusive Care for the Elderly (PACE) Organizations
Mar 17, 2020

CMS Announces New Measures to Protect Nursing Home Residents from COVID-

ensure they are prepared to address the COVID-19 threat. In the initial wave of surveys during the week of March 30, CMS found that 36 percent of facilities inspected in recent days did not follow proper hand washing guidelines and 25 percent failed to demonstrate proper use of personal protective equipment (PPE). Both of these are longstanding infection control measures that all nursing homes are expected to follow per Federal regulation. CMS is continuing to conduct targeted infection control inspections to ensure nursing homes are prepared to confront COVID-19 and keep their residents safe. Finally, Medicare is now covering COVID-19 testing when furnished to eligible beneficiaries by certified laboratories. These laboratories may also choose to enter facilities to conduct COVID-19 testing.

The recommendations announced today include:

- Nursing homes should immediately ensure that they are complying with all CMS and CDC guidance related to infection control.
- As nursing homes are a critical part of the healthcare system, and because of the ease of spread in long term care facilities and the severity of illness that occurs in residents with COVID-19, CMS/CDC urges State and local leaders to consider the needs of long term care

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Mar 13, 2020

Contact us

CMS News and Media Group
Catherine Howden, Director
Kelly Ceballos, Deputy Director

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facilities with respect to supplies of PPE and COVID-19 tests.

- Nursing homes should immediately implement symptom screening for all staff, residents, and visitors – including temperature checks.
- Nursing homes should ensure all staff are using appropriate PPE when they are interacting with patients and residents, to the extent PPE is available and per CDC guidance on conservation of PPE.
- To avoid transmission within nursing homes, facilities should use separate staffing teams for residents to the best of their ability, and, as President Trump announced at the White House today, the administration urges nursing homes to work with State and local leaders to designate separate facilities or units within a facility to separate COVID-19 negative residents from COVID-19 positive residents and individuals with unknown COVID-19 status.

"The Trump Administration is calling on the nursing home industry and state and local leaders to join us by taking action now to ensure the safety of their residents, who are among our most vulnerable citizens. The Administration urges them to carefully review our recommendations, and implement them immediately," said CMS Administrator Seema Verma.

Today's recommendations will help State and local governments, and nursing

homes, as they consider creative ways to stop the spread of the virus, such as designating units within facilities – or entire facilities – solely for residents with confirmed COVID-19. An example of such an arrangement is in Wilmington, Massachusetts, in which a 142-bed facility has been designated as a solely COVID-19-positive facility. Residents across the region who are infected with COVID-19 can be moved to this facility to receive appropriate care and avoid transmitting the virus within their facilities. This approach also eases the challenges of preventing transmission, like extensive PPE usage and isolation practices, for individual facilities. The Massachusetts arrangement, developed in coordination with the state's government, is a prime example of the arrangements envisioned in the recommendations announced today.

The recommendations also speak to enhanced screening and transmission prevention practices. Previous CMS guidance, developed with CDC and issued in mid-March, advised nursing homes to restrict all but the most urgent visitors and staff. Today's guidance builds on this by recommending temperature screenings for all visitors and that all staff utilize adequate PPE when interacting with patients, to the extent PPE is available.

Nursing homes are unique in the healthcare system because, unlike other

healthcare facilities, they are full-time homes as well as settings of care. Importantly, nursing home residents, given their advanced age and corresponding health issues, are at particular risk of complications arising from COVID-19. Because they are large concentrations of particularly vulnerable individuals, nursing homes have been a major focus for the Trump Administration in its aggressive efforts to combat the virus.

This action, and earlier CMS actions in response to COVID-19, are part of the ongoing White House Coronavirus Task Force efforts. To keep up with the important work the Task Force is doing in response to COVID-19, visit www.coronavirus.gov. For a complete and updated list of CMS actions, and other information specific to CMS, please visit the Current Emergencies Website.

###

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Exhibit B

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Morbidity and Mortality Weekly Report (*MMWR*)

CDC

Community Mitigation Guidelines to Prevent Pandemic Influenza — United States, 2017

Recommendations and Reports / April 21, 2017 / 66(1);1–34

Free CE

Noreen Qualls, DrPH[1]; Alexandra Levitt, PhD[2]; Neha Kanade, MPH[1,3]; Narue Wright-Jegede, MPH[1,4]; Stephanie Dopson, ScD[5]; Matthew Biggerstaff, MPH[6]; Carrie Reed, DSc[6]; Amra Uzicanin, MD[1] (View author affiliations)

View suggested citation

Summary

When a novel influenza A virus with pandemic potential emerges, nonpharmaceutical interventions (NPIs) often are the most readily available interventions to help slow transmission of the virus in communities, which is especially important before a pandemic vaccine becomes widely available. NPIs, also known as community mitigation measures, are actions that persons and communities can take to help slow the spread of respiratory virus infections, including seasonal and pandemic influenza viruses.

These guidelines replace the 2007 *Interim Pre-pandemic Planning Guidance: Community Strategy for Pandemic Influenza Mitigation in the United States — Early, Targeted, Layered Use of Nonpharmaceutical Interventions* (https://stacks.cdc.gov/view/cdc/11425). Several elements remain unchanged from the 2007 guidance, which described recommended NPIs and the supporting rationale and key concepts for the use of these interventions during influenza pandemics. NPIs can be phased in, or layered, on the basis of pandemic severity and local transmission patterns over time. Categories of NPIs include personal protective measures for everyday use (e.g., voluntary home isolation of ill persons, respiratory etiquette, and hand hygiene); personal protective measures reserved for influenza pandemics (e.g., voluntary home quarantine of exposed household members and use of face masks in community settings when ill); community measures aimed at increasing social distancing (e.g., school closures and dismissals, social distancing in workplaces, and postponing or cancelling mass gatherings); and environmental measures (e.g., routine cleaning of frequently touched surfaces).

Several new elements have been incorporated into the 2017 guidelines. First, to support updated recommendations on the use of NPIs, the latest scientific evidence available since the influenza A (H1N1)pdm09 pandemic has been added. Second, a summary of lessons learned from the 2009 H1N1 pandemic response is presented to underscore the importance of broad and flexible prepandemic planning. Third, a new section on community engagement has been included to highlight that the timely and effective use of NPIs depends on community acceptance and active participation. Fourth, to provide new or updated pandemic assessment and planning tools, the novel influenza virus pandemic intervals tool, the Influenza Risk Assessment Tool, the Pandemic Severity Assessment Framework, and a set of prepandemic planning scenarios are described. Finally, to facilitate implementation of the updated guidelines and to assist states and localities with prepandemic planning and decision-making, this report links to six supplemental prepandemic NPI planning guides for different community settings that are available online (https://www.cdc.gov/nonpharmaceutical-interventions).

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Introduction

Nonpharmaceutical interventions (NPIs) are strategies for disease, injury, and exposure control (https://www.cdc.gov/phpr/capabilities/DSLR_capabilities_July.pdf). They include actions that persons and communities can take to help slow the spread of respiratory viruses (e.g., seasonal and pandemic influenza viruses). These actions include personal protective measures for everyday use (e.g., staying home when ill, covering coughs and sneezes, and washing hands often) and communitywide measures reserved for pandemics and aimed at reducing opportunities for exposure (e.g., coordinated closures and dismissals of child care facilities and schools and cancelling mass gatherings). When a novel influenza A virus with pandemic potential emerges, NPIs can be used in conjunction with available pharmaceutical interventions (antiviral medications) to help slow its transmission in communities, especially when a vaccine is not yet widely available. Given current vaccine technology, a pandemic vaccine might not be available for up to 6 months (https://www.fda.gov/%20ForConsumers/ConsumerUpdates/ucm336267.htm). NPIs can be used before a pandemic is declared in areas where a novel influenza A virus is detected and during a pandemic.

These 2017 guidelines provide evidence-based recommendations on the use of NPIs in mitigating the effects of pandemic influenza. These guidelines update and expand the 2007 strategy (https://stacks.cdc.gov/view/cdc/11425).*

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Purpose

The purpose of these guidelines is to help state, tribal, local, and territorial health departments with prepandemic planning and decision-making by providing updated recommendations on the use of NPIs. These recommendations have incorporated lessons learned from the federal, state, and local responses to the influenza A (H1N1)pdm09 virus pandemic (hereafter referred to as the 2009 H1N1 pandemic) and findings from research. Communities, families and individuals, employers, and schools can create plans that use these interventions to help slow the spread of a pandemic and prevent disease and death.

Specific goals for implementing NPIs early in a pandemic include slowing acceleration of the number of cases in a community, reducing the peak number of cases during the pandemic and related health care demands on hospitals and infrastructure, and decreasing overall cases and health effects (Figure 1). When a pandemic begins, public health authorities need to decide on an appropriate set of NPIs for implementation and to reiterate the importance of personal protective measures for everyday use (e.g., voluntary home isolation of ill persons [staying home when ill], respiratory etiquette, and hand hygiene) and environmental cleaning measures (e.g., routine cleaning of frequently touched surfaces), which are recommended at all times for prevention of respiratory illnesses (Table 1). Personal protective measures reserved for pandemics (e.g., voluntary home quarantine of exposed household members [staying home when a household member is ill] and use of face masks by ill persons) also might be recommended (Table 1). A more difficult decision is how and when to implement community-level NPIs that might be warranted but are more disruptive (e.g., temporary school closures and dismissals, social distancing in workplaces and the community, and cancellation of mass gatherings) (Table 1). These decisions are made by state and local officials on the basis of conditions in the applicable jurisdictions, with guidance from CDC (according to pandemic severity and potential efficacy) and governing authorities (*1*). Prepandemic planning, along with community engagement, is an essential component of these decisions (Table 2).

The decision regarding whether and when to recommend additional NPIs is another component (Table 3). State and local public health departments might use certain influenza surveillance indicators to help decide when to consider implementing NPIs such as school closures and dismissals and other social distancing measures in schools, workplaces, and public settings during an influenza pandemic. The choice of influenza surveillance indicators might differ between states and localities, depending on the availability and capacity of their public health resources. Examples of possible influenza surveillance indicators include additional patient visits to health care providers for influenza-like illness (ILI) and increased geographic spread of influenza within a state. Indicators for school closures and dismissals might include increased school absenteeism rates or the earliest laboratory-confirmed influenza cases among students, teachers, or staff members. Indicators that might help confirm that NPI implementation should continue include increased influenza-associated hospitalizations or increases in adult or pediatric deaths attributed to influenza. Additional information about NPI prepandemic planning is available (supplementary Chapter 1 https://stacks.cdc.gov/view/cdc/44313).

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Background

An influenza pandemic occurs when a novel virus emerges for which the majority of the population has little or no immunity. Influenza pandemics are facilitated by sustained human-to-human transmission, and the infection spreads worldwide over a relatively short period (*2*). The first influenza pandemic of the 21st century began in 2009, 2 years after the 2007 strategy for prepandemic planning was published. Lessons learned during the response to the 2009 H1N1 pandemic underscored the importance of a flexible approach to the use of NPIs, particularly during the early stages of a pandemic, and led to the development of new tools for assessing pandemic severity and prepandemic planning (Box 1).

Lessons Learned from the 2009 H1N1 Pandemic Response

The 2009 H1N1 pandemic was a reminder to be prepared for the unpredictable nature of pandemics. Knowing in advance which subtype of pandemic virus will emerge is impossible, as is where and when it will emerge, how quickly the virus will spread, how severe the illness will be, and who will be the most affected. Because of this unpredictability, prepandemic planning must be broad and flexible.

The 2007 strategy for prepandemic planning was developed with the assumption that the next influenza pandemic would be severe, like the 1957 pandemic, which was characterized by high transmissibility and high clinical severity. When the 2007 strategy was developed, the primary concern was that a pandemic virus might evolve from the highly pathogenic avian influenza A (H5N1) virus, a virus that reemerged in Asia in 2003 in domestic poultry and spread to Africa, the Middle East, and Europe among poultry, with sporadic zoonotic transmission (*37*). Moreover, CDC thought that this virus would most likely emerge overseas, providing the United States with time to prepare for a domestic response, including making use of prepandemic H5N1 vaccine in CDC's Strategic National Stockpile. Instead, the 2009 pandemic influenza A virus turned out to be a novel H1N1 virus that appears to have emerged in southern Mexico and was first identified in two persons in California (*13*). Although the 2009 H1N1 pandemic in the United States was moderate in terms of overall morbidity and mortality among the U.S. general population, severe outcomes from H1N1pdm09 virus infection were more common among children, young adults, and specific groups at risk for serious complications (e.g., pregnant women) than among older adults (Box 1).

Although the emergence of the H1N1pdm09 virus prompted development of pandemic vaccines, a pandemic vaccine was not available until October 2009, 6 months after the initial report that identified the pandemic virus. In addition, another 2 months were required (December 2009) for sufficient stocks to be manufactured, distributed, and available to vaccinate several population groups, including school-aged children and persons living with or caring for infants aged <6 months, as recommended by the Advisory Committee on Immunization Practices (ACIP).† Even though work is ongoing to accelerate the pace of development, distribution, and administration of a vaccine during future pandemics, this experience reaffirmed the importance of the use of NPIs in the early stages of a pandemic before a well-matched vaccine is widely available (i.e., vaccines produced using a virus that is very similar to the circulating virus).

Another lesson learned about NPI implementation during the 2009 H1N1 pandemic was that rapidly changing guidance can create confusion and difficulties during implementation (Box 1) (*30,31*). Nevertheless, field studies found that school-related NPIs, including school closures recommended to mitigate the impact of the 2009 H1N1 pandemic during spring 2009, were considered acceptable and feasible for most parents and caregivers, even when parents had to miss work and in the absence of free or reduced-cost school lunches for students (*28,38–41*). Other interventions that reduced the spread of H1N1pdm09 virus in some communities included hand hygiene (*42*), regularly scheduled school summer breaks (*19*), and social distancing measures such as cancelling mass gatherings and closing public places (*22*).

Community Engagement

The 2009 H1N1 pandemic underscored that effective prepandemic planning requires the involvement of public health and local leaders, employers, organizations, and stakeholders and is essential to ensure timely and effective use of NPIs to limit disease spread during a pandemic (Box 2). Effective use of NPIs depends on the acceptance and participation of individual persons who implement personal protective measures and of communities that implement communitywide measures such as temporary school closures (https://www.cdc.gov/phpr/capabilities/DSLR_capabilities_July.pdf).

The 2007 guidance took into account the results of a 2006 opinion poll conducted with a representative national sample of 1,697 adults aged ≥18 years. The results indicated that when faced with an outbreak of pandemic influenza, the majority of persons in the United States would be willing to make major changes in their lives and cooperate with public health recommendations on the use of NPIs (http://archive.sph.harvard.edu/press-releases/2006-releases/press10262006.html). Findings were similar in a follow-up study during the 2009–2010 H1N1 pandemic (Box 1) (https://www.hsph.harvard.edu/horp/project-on-the-public-response-to-h1n1).

For example, in 2006, 85% of the respondents said that they and all members of their household would stay home for 7–10 days if another household member were ill with pandemic influenza. The H1N1 opinion polls also identified barriers to implementation of NPIs among persons and communities (e.g., the ability to stay home when ill, job security, and income protection) (https://www.hsph.harvard.edu/horp/project-on-the-public-response-to-h1n1). States and local councils could establish local planning councils or hold public engagement meetings that address these and other issues related to public health preparedness, public education, and planning. States and local communities also can draw on planning guidance provided in the CDC Public Health Preparedness Capabilities: National Standards for State and Local Planning, which lists NPIs as one of 15 capabilities (https://www.cdc.gov/phpr/capabilities/DSLR_capabilities_July.pdf). Additional information about prepandemic planning and NPI community engagement is available (supplementary Chapter 1 https://stacks.cdc.gov/view/cdc/44313).

New Tools for Prepandemic Planning and Pandemic Assessment

Novel Influenza Virus Pandemic Intervals

In 2014, CDC updated its 2008 guidance on pandemic intervals to include six intervals that describe influenza pandemic progression in a way that supports flexible prepandemic preparedness and response. The intervals include 1) investigation of novel influenza cases, 2) recognition of potential for ongoing transmission, 3) initiation, 4) acceleration, 5) deceleration of the pandemic wave, and 6) preparation for a future pandemic wave (*43*). These intervals can be used during prepandemic planning and can serve as a platform for public health decision-making and actions during the beginning of a potential influenza pandemic. Each interval is associated with particular response activities, including implementation of select NPIs during the initiation and acceleration intervals and coordinated discontinuation of select community-level NPIs reserved for pandemics during the deceleration interval (Figure 2) (Table 4). Although the six-interval framework describes the sequence of pandemic disease evolution over time, the framework does not characterize the transmissibility of the virus or the clinical severity of the outbreak. Therefore, CDC has developed additional tools for pandemic planning and response, including the Influenza Risk Assessment Tool (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313; https://www.cdc.gov/flu/pandemic-resources/tools/risk-assessment.htm) and the Pandemic Severity Assessment Framework (PSAF). Additional information about the pandemic intervals is available (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313).

Pandemic Severity Assessment Framework

An influenza pandemic can range from mild to extremely severe in terms of clinical severity and transmission rate. When a pandemic emerges, public health authorities should assess its projected impact and recommend rapid action to reduce virus transmission, protect populations at high risk for complications, and minimize societal disruption. As observed during the 2009 H1N1 pandemic response, attack rates and case-fatality ratios can be difficult to measure early in a pandemic because of variations in care-seeking behavior and testing practices; not everyone seeks care for their illness, and not everyone is tested and receives a diagnosis of pandemic influenza. As a result, severe cases might be more likely to be reported, resulting in an overestimate of the case-hospitalization or case-fatality ratio. Tools for prepandemic planning have been updated and augmented based on that experience, and the Pandemic Severity Index in the 2007 guidance has been replaced with PSAF. PSAF uses multiple clinical and epidemiologic indicators to provide a more comprehensive assessment of the transmissibility and clinical severity of an emerging pandemic. Whereas the Pandemic Severity Index was based on the assumption that a future pandemic would cause an illness rate of 30% in the U.S. population and relied on an assessment of case-fatality ratios to determine severity of an evolving pandemic, PSAF incorporates multiple measures of clinical severity (e.g., case-fatality ratios, case-hospitalization ratios, and deaths-hospitalizations ratios) and viral transmissibility (e.g., secondary household attack rates, school attack rates, workplace attack rates, community attack rates, or all of these, as well as rates of emergency department and outpatient visits for ILI) (*44*).

When a pandemic begins, in the United States or anywhere in the world, CDC makes an initial assessment of viral transmissibility and clinical severity on the basis of these multiple PSAF measures (Table 5) (*44*). On the basis of the initial assessment, CDC recommends that affected U.S. jurisdictions respond (and other jurisdictions prepare to respond). Although data are limited during the initial 3–4 weeks after the emergence of a pandemic virus, these early data are compiled into a broad, preliminary assessment. CDC uses PSAF scores of viral transmissibility and clinical severity to place the pandemic within one of four assessment quadrants (Figure 3). Depending on the surveillance capacity in the location where the novel virus emerges and first spreads, 4–8 weeks or longer might be required to accrue sufficient data for a refined assessment of an evolving pandemic. Once data are available, the refined assessment is used to more precisely characterize the clinical severity and transmissibility of the pandemic virus (Figure 4) (Table 6). These initial and refined assessments of pandemic severity are used, in coordination with state and local public health partners, to guide the use of NPI measures. Additional information about PSAF is available (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313).

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Methods

Guidelines Development Process

This 2017 update consists of three separate documents: this report and two supplementary documents (https://stacks.cdc.gov/view/cdc/44313 and https://stacks.cdc.gov/view/cdc/44314). This report provides a brief introduction to pandemic influenza and NPIs; describes the 2007 strategy and the purpose of the updates, particularly after the 2009 H1N1 pandemic; outlines the methods used to develop this update and describe the evidence considered for NPI use during an influenza pandemic; presents CDC's NPI recommendations; and discusses key areas for further NPI research. The two supplementary documents contain more specific and detailed information about pandemic influenza and NPIs. One document (Technical Report 1 https://stacks.cdc.gov/view/cdc/44313) is divided into chapters and provides an introduction to and overview of NPIs, a description of the new tools developed for pandemic influenza planning and assessment, and a toolbox describing the NPI evidence base, implementation issues, and research gaps. The second document (Technical Report 2 https://stacks.cdc.gov/view/cdc/44314) consists of several appendices that provide a glossary of terms, a detailed description of the methods used for developing the NPI recommendations, a comprehensive summary table of the NPI body of evidence, and a list of tools and resources for pandemic influenza planning and preparedness.

This 2017 update was developed through collaboration involving input from several sources, including peer-reviewed scientific literature, current research, CDC subject-matter experts, and external stakeholders (e.g., federal agencies, public health officials, and business and education partners). Development of these updated guidelines involved participation by multiple CDC groups (e.g., the Community Mitigation Guidelines Work Group and the coordination, abstraction, and consultation teams), as well as a group of external stakeholders who reviewed a document, summarizing the overall direction and key principles and concepts of the guidelines. Input from the work group members, subject-matter experts, and stakeholders was considered and incorporated during the creation of the 2017 planning guidelines. The guidelines were developed during October 2011–October 2016 (Table 7). The complete list of contributors and their roles in the process are available (supplementary Appendix 2 https://stacks.cdc.gov/view/cdc/44314).

Use of NPIs During Influenza Pandemics

Ten years ago, when the 2007 strategy was being developed, the evidence for the use of NPIs during influenza pandemics was limited, consisting primarily of historical analyses and contemporary observations rather than controlled scientific studies (*45,46*). These analyses and observations were supplemented by modeling studies that used historical data to evaluate NPI use in U.S. cities during the 1918 pandemic (*47,48*) or that simulated pandemic scenarios as they might occur in the future (*49–51*). The simulations, like the historical analyses, generally supported the effectiveness of early, targeted, and phased-in (layered) use of multiple NPIs§ in preventing spread of disease, especially when used in combination with antiviral medications (*46,49*). This conclusion seemed plausible, confirming the presumption that individual, partially effective NPIs act in complementary ways to decrease various factors that facilitate the spread of influenza under different circumstances and settings (*52*). However, the NPI modeling studies had substantial limitations, including lack of data supporting assumptions about the effectiveness of individual NPIs, economic and social costs of NPIs, and likely rates of compliance (*46,49,53*).

In 2016, the evidence supporting the effectiveness of NPIs, both when used alone and in combination, was more substantial and included controlled studies evaluating different NPIs. New modeling studies based on data collected during the 2009 H1N1 pandemic response also became available. This update is based on approximately 191 journal articles written in English and published from 1990 through September 2016 that focused on personal protective measures in general; school closure effectiveness and unintended consequences; school absenteeism; spread of disease in child care facilities, colleges, and universities; impact of mass gatherings; and role and impact of NPIs in non–health care workplace settings. These articles were reviewed, abstracted, and synthesized. To assess the strength of the evidence, a five-step NPI rating scheme process was developed by adapting and applying the approach of the *Guide to Community Preventive Services* (*The Community Guide*) (https://www.thecommunityguide.org). Additional information about the NPI rating scheme process is available (supplementary Appendices 3 and 4 https://stacks.cdc.gov/view/cdc/44314).

The selected articles were organized into three groups: 1) personal NPIs (personal protective measures for everyday use and personal protective measures reserved for influenza pandemics); 2) community NPIs (social distancing measures and school closures and dismissals); and 3) environmental NPIs (surface cleaning measures) (Table 8). Key steps included selecting the relevant literature, abstracting and synthesizing the evidence, and assessing the evidence quality (both individual study quality and the quality of the body of evidence). A recommendation was formulated based on the evidence of effectiveness for each NPI. The strength of NPI recommendations took into consideration the effectiveness of the intervention, the ease of implementation (including unwanted consequences), and the importance of the intervention as a public health strategy. Additional information about the NPI evidence base is available (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313 and supplementary Appendix 5 https://stacks.cdc.gov/view/cdc/44314).

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Recommendations on the Use of Personal, Community, and Environmental NPIs

NPIs routinely recommended for prevention of respiratory virus transmission, such as seasonal influenza, include personal protective measures for everyday use (i.e., voluntary home isolation of ill persons, respiratory etiquette, and hand hygiene) and environmental surface cleaning measures (i.e., routine cleaning of frequently touched surfaces and objects). During an influenza pandemic, these NPIs are recommended regardless of the pandemic severity level. Additional personal and community NPIs also might be recommended. Personal protective measures reserved for pandemics include voluntary home quarantine of exposed household members and use of face masks in community settings when ill. Community NPIs might include temporary closures or dismissals of child care facilities and schools with students in grades kindergarten through 12 (K–12), as well as other social distancing measures that increase the physical space between people (e.g., workplace measures such as replacing in-person meetings with teleconferences or modifying, postponing, or cancelling mass gatherings) (Figure 5) (Table 1). Local decisions about NPI selection and timing involve consideration of overall pandemic severity and local conditions (*1*) and require flexibility and possible modifications as the pandemic progresses and new information becomes available.

Updated recommendations on the use of NPIs to help slow the spread and decrease the impact of an influenza pandemic are provided, as is information on the rationale for using each NPI as part of a comprehensive public health strategy for pandemic response and the appropriate settings and use for each NPI according to the severity of the pandemic (Table 9).¶ The recommendations that follow are considered an update to the existing recommendations in the 2007 guidance because the same set of NPIs has been maintained and recommended for use early in a pandemic. However, the difference between the guidance issued in 2007 and in 2017 is the clear delineation of NPIs into two categories: 1) NPIs recommended at all times and 2) NPIs recommended for use only during pandemics (based on the level of pandemic severity and local conditions). The 2017 update also provides additional evidence to support the NPI recommendations.

Personal NPIs

NPIs that can be implemented by individual persons include the following:

- **Personal protective measures for everyday use:** These include voluntary home isolation of ill persons, respiratory etiquette, and hand hygiene.
- **Personal protective measures reserved for pandemics:** These include voluntary home quarantine of exposed household members and use of face masks in community settings when ill.

Personal Protective Measures for Everyday Use

Personal protective measures are preventive actions that can be used daily to slow the spread of respiratory viruses (https://www.cdc.gov/nonpharmaceutical-interventions/personal/index.html; supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313). These measures include the following:

- **Voluntary home isolation (i.e., staying home when ill or self-isolation):** Persons with influenza stay home for at least 24 hours after a fever or signs of a fever (chills, sweating, and feeling warm or flushed)** are gone (https://www.cdc.gov/flu/protect/preventing.htm), except to obtain medical care or other necessities.†† To ensure that the fever is gone, patients' temperature should be measured in the absence of a medication that lowers fever (e.g., acetaminophen or ibuprofen). In addition to fever, common influenza symptoms include cough or chest discomfort, muscle or body aches, headache, and fatigue. Persons also might experience sneezing, a runny or stuffy nose, sore throat, vomiting, and diarrhea (https://www.cdc.gov/flu/consumer/symptoms.htm).
- **Respiratory etiquette:** Persons cover coughs and sneezes, preferably with a tissue, and then dispose of tissues and disinfect hands immediately after a cough or sneeze, or (if a tissue is not available) cough or sneeze into a shirt sleeve. Touching the eyes, nose, and mouth should be avoided to help slow the spread of germs (https://www.cdc.gov/flu/protect/covercough.htm).
- **Hand hygiene:** Persons perform regular and thorough hand washing with soap and water (or use alcohol-based hand sanitizers containing at least 60% ethanol or isopropanol when soap and water are not available).

Rationale for use as a public health strategy. Most persons infected with an influenza virus might become infectious 1 day before the onset of symptoms and remain infectious for up to 5–7 days after becoming ill (*54,55*). However, studies found that infants and immunocompromised persons might shed influenza viruses for prolonged periods (up to 21 days and a mean of 19 days, respectively) (*56,57*). The effectiveness of personal protective measures depends on their ability to interrupt virus transmission from one person to another. Voluntary home isolation, which is a form of patient isolation, prevents an ill person from infecting other people outside of their household.§§ Respiratory etiquette reduces the dispersion of droplets contaminated with influenza virus being propelled through the air by coughing or sneezing. Hand hygiene reduces the transmission of influenza viruses that occurs when one person touches another (e.g., with a contaminated hand). Contamination also can occur through self-inoculation via fomite transmission (indirect contact transmission) when persons touch a contaminated surface and then touch their nose with a contaminated hand. A study conducted in households in Bangkok, Thailand, found that increased handwashing reduced surface contamination with influenza virus, which lowered the potential for self-inoculation via fomite transmission (*58*). Additional studies found that influenza viruses can remain viable on the human hand for roughly 3–5 minutes (*59*) and that influenza viruses can remain on fingers for 30 minutes after contamination (*60*).

Settings and use. Voluntary home isolation involves persons remaining at home when ill with influenza. Respiratory etiquette and hand hygiene are recommended in homes and in all other community settings, including schools and workplaces. All three personal protective measures are considered everyday preventive actions that should be implemented year-round but that are especially important during annual influenza seasons and influenza pandemics (Table 10). Use of these personal protective measures might result in some secondary (unintended or unwanted) consequences (e.g., concerns about job security for ill persons who lack paid sick leave or skin irritations due to frequent hand washing).

CDC recommendations

Voluntary home isolation: CDC recommends voluntary home isolation of ill persons (staying home when ill) year-round and especially during annual influenza seasons and influenza pandemics.

Respiratory etiquette and hand hygiene: CDC recommends respiratory etiquette and hand hygiene in all community settings, including homes, child care facilities, schools, workplaces, and other places where people gather, year-round and especially during annual influenza seasons and influenza pandemics.

Personal Protective Measures Reserved for Pandemics

Voluntary home isolation, respiratory etiquette, and hand hygiene are recommended during both annual influenza seasons and influenza pandemics. Additional personal protective measures that might be recommended during pandemics include voluntary home quarantine of exposed household members and the use of face masks in community settings when ill. These measures might contribute to reductions in transmission of pandemic influenza viruses when the level of pandemic severity and local conditions warrant their use (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313).

Voluntary Home Quarantine

Voluntary home quarantine of non-ill household members of persons with influenza (also called self-quarantine or household quarantine) helps prevent disease spread from households to schools, workplaces, and other households because those household members have been exposed to the influenza virus. Exposed household members of symptomatic persons (with confirmed or probable pandemic influenza) should stay home for up to 3 days (the estimated incubation period for seasonal influenza) (*61*) starting from their initial contact with the ill person. If they then become ill, they should practice voluntary home isolation (i.e., they should remain at home until recovered as discussed previously; https://www.cdc.gov/quarantine/index.html). For certain exposed household members (e.g., those at high risk for influenza complications or with severe immune deficiencies), guidelines should be consulted regarding the prophylactic use of antiviral medications (https://www.cdc.gov/flu/professionals/antivirals/index.htm).

Rationale for use as a public health strategy. Voluntary home quarantine might help slow a pandemic by reducing community transmission from households with a person who has influenza because the exposed household members are at increased risk for infection. Furthermore, certain infected (but not yet symptomatic) household members could begin shedding influenza virus at least a day before exhibiting symptoms and could infect friends, neighbors, and others in the community (e.g., at school or work) before becoming symptomatic. Therefore, all members of a household with a symptomatic person (with confirmed or probable pandemic influenza) might be asked to stay home for a specified period of time (up to 3 days) to assess for early signs and symptoms of pandemic influenza virus infection. If other household members become ill during this period, then the time for voluntary home quarantine might need to be extended for another incubation period. The evidence for voluntary home quarantine, particularly when used in combination with other NPIs, includes a systematic literature review, historical analyses of the 1918 pandemic, and mathematical modeling studies (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313 and supplementary Appendix 5 https://stacks.cdc.gov/view/cdc/44314).

Settings and use. Voluntary home quarantine of exposed household members might be recommended during severe, very severe, or extreme influenza pandemics (Table 10) to help reduce the chance of transmitting the virus to others outside of the household. Advance planning is needed to minimize potential secondary consequences for persons who have special cultural, economic, legal, mental, physical, or social status needs (e.g., older adults who depend on necessary community-based services such as home-delivered meals and transportation to health care services). Other secondary consequences might include missed work and loss of income for persons whose employers do not have paid sick leave policies that include home quarantine during pandemics.

CDC recommendations

Voluntary home quarantine: CDC might recommend voluntary home quarantine of exposed household members as a personal protective measure during severe, very severe, or extreme influenza pandemics in combination with other personal protective measures such as respiratory etiquette and hand hygiene. If a member of the household is symptomatic with confirmed or probable pandemic influenza, then all members of the household should stay home for up to 3 days (the estimated incubation period for seasonal influenza)¶¶ starting from their initial contact with the ill person, to monitor for influenza symptoms.

Use of Face Masks in Community Settings

Face masks (disposable surgical, medical, or dental procedure masks) are widely used by health care workers to prevent respiratory infections both in health care workers and patients. They also might be worn by ill persons during severe, very severe, or extreme pandemics to prevent spread of influenza to household members and others in the community. However, little evidence supports the use of face masks by well persons in community settings, although some trials conducted during the 2009 H1N1 pandemic found that early combined use of face masks and other NPIs (such as hand hygiene) might be effective (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313).

Rationale for use as a public health strategy. Face masks provide a physical barrier that prevents the transmission of influenza viruses from an ill person to a well person by blocking large-particle respiratory droplets propelled by coughing or sneezing. Face mask use by well persons is not routinely needed in most situations to prevent acquiring the influenza virus. However, use of face masks by well persons might be beneficial in certain situations (e.g., when persons at high risk for influenza complications cannot avoid crowded settings or parents are caring for ill children at home). Face mask use by well persons also might reduce self-inoculation (e.g., touching the nose with the hand after touching a contaminated surface).

Settings and use. Disposable surgical, medical, and dental procedure masks are used widely in health care settings to prevent exposure to respiratory infections. Face masks have few secondary consequences (e.g., discomfort or difficulty breathing) when worn properly and consistently, and face masks sized for children are available. (Additional information about face masks is available at https://www.fda.gov/medicaldevices/productsandmedicalprocedures/generalhospitaldevicesandsupplies/personalprotectiveequipment/ucm055977.htm and https://www.osha.gov/Publications/respirators-vs-surgicalmasks-factsheet.html.)

CDC recommendations

Use of face masks by ill persons: CDC might recommend the use of face masks by ill persons as a source control measure during severe, very severe, or extreme influenza pandemics when crowded community settings cannot be avoided (e.g., when adults and children with influenza symptoms seek medical attention) or when ill persons are in close contact with others (e.g., when symptomatic persons share common spaces with other household members or symptomatic postpartum women care for and nurse their infants). Some evidence indicates that face mask use by ill persons might protect others from infection.

Use of face masks by well persons: CDC does not routinely recommend the use of face masks by well persons in the home or other community settings as a means of avoiding infection during influenza pandemics except under special, high-risk circumstances (https://www.cdc.gov/flu/professionals/infectioncontrol/maskguidance.htm). For example, during a severe pandemic, pregnant women and other persons at high risk for influenza complications might use face masks if unable to avoid crowded settings, especially if no pandemic vaccine is available. In addition, persons caring for ill family members at home (e.g., a parent of a child exhibiting influenza symptoms) might use face masks to avoid infection when in close contact with a patient, just as health care personnel wear masks in health care settings.

Community NPIs

NPIs that can be implemented by communities include the following:

- **School closures and dismissals:** These include temporary closures and dismissals of child care facilities, K–12 schools, and institutions of higher education.
- **Social distancing measures:** These include measures for schools, workplaces, and mass gatherings.

School Closures and Dismissals

In the event of a pandemic, state and local public health authorities play an important role in protecting the school community and should establish and maintain partnerships with district and school leaders, school emergency operations planning teams, and local municipality leaders (e.g., mayors). Public health authorities are a credible source of information, have multiple (often free) resources available for information awareness campaigns, and provide guidance for increasing school response measures. Depending on the severity of the pandemic, these measures might range from everyday preventive actions to preemptive, coordinated school closures and dismissals. A school closure means closing a school and sending all the students and staff members home, whereas during a school dismissal, a school might stay open for staff members while the children stay home. Preemptive school dismissals can be used to disrupt transmission of influenza before many students and staff members become ill. Coordinated dismissals refer to the simultaneous or sequential closing of schools in a jurisdiction. Thus, preemptive, coordinated school closures and dismissals can be used early during an influenza pandemic to prevent virus transmission in schools and surrounding communities by reducing close contact among the following groups (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313):

- Children in child care centers and preschools
- School-aged children and teens in K–12 schools
- Young adults in institutions of higher education

During a dismissal, the school facilities are kept open, which allows teachers to develop and deliver lessons and materials, thus maintaining continuity of teaching and learning, and allows other staff members to continue to provide services and help with additional response efforts. School closures and dismissals might be coupled with social distancing measures (e.g., cancelling sporting events and other mass gatherings) to reduce out-of-school social contact among children when schools are closed.

Rationale for use as a public health strategy. Preventing the spread of disease in educational settings among children and young adults reduces the risk for infection for these age groups and slows virus transmission in the community. Components of the strategy might include preemptive, coordinated school closures and dismissals implemented during the earliest stages of a pandemic, before many students and staff members become ill. Preemptive, coordinated dismissals can be implemented by the following facilities for the following reasons:

- Child care facilities and K–12 schools
  - Children have higher influenza attack rates than adults (*62*) and are infectious for a longer period than adults (*63,64*).
  - Influenza transmission is common in schools and contributes to school absenteeism and parental absenteeism from work (*65,66*).
  - The presence of school-aged children in a household is a risk factor for influenza virus infection in families (*62,65,67*).
  - Social contact and mixing patterns among school-aged children differ substantially depending on the grade and school level, during various periods of the school day, between weekdays and weekends, and between regular school terms and holiday breaks (*68–71*). Physical floor plans and intergrade activities (e.g., cafeteria size and lunch breaks) also can affect in-school social mixing (*68*).
  - Schoolchildren can introduce the influenza virus into a community, leading to increased rates of illness among their household or community contacts (*72–74*).
- Institutions of higher education
  - Influenza outbreaks on college and university campuses typically have high attack rates (44%–73%) (*75–78*) and cause substantial morbidity (*79,80*). For example, during the 2009 H1N1 pandemic, influenza spread rapidly through a university campus within 2 weeks (*81*); on another residential campus, one infected freshman initiated an outbreak that resulted in 226 laboratory-confirmed cases. Freshmen were the main facilitators of the spread of the H1N1pdm09 virus because of their higher number and frequency of social contacts (*82*).
  - Influenza is more prevalent among residential students at boarding schools and colleges than among nonresidential students (*78,83*).
  - ILIs are common among college and university students and are associated with increased health care use, decreased health status, and impaired school performance (*84*).

Implementation of preemptive, coordinated school closures and dismissals during an evolving influenza pandemic might have one or more of the following three public health objectives***:

- **Objective 1:** To gain time for an initial assessment of transmissibility and clinical severity of the pandemic virus in the very early stage of its circulation in humans (closures for up to 2 weeks)
- **Objective 2:** To slow down the spread of the pandemic virus in areas that are beginning to experience local outbreaks and thereby allow time for the local health care system to prepare additional resources for responding to increased demand for health care services (closures up to 6 weeks)
- **Objective 3:** To allow time for pandemic vaccine production and distribution (closures up to 6 months)

Two other types of school closures and dismissals might be implemented during a pandemic for public health or institutional reasons. These interventions do not slow disease spread in the community; therefore, they are not considered NPIs. These include the following:

- **Selective school closures and dismissals:** These might be implemented by schools that serve students at high risk for complications from infection with influenza,††† especially when transmission rates are high. For example, a school that serves children with certain medical conditions or pregnant teens might decide to close while other schools in the area remain open. In addition, some communities or early childhood programs might consider closing child care facilities to help decrease the spread of influenza among children aged <5 years. Selective dismissals are intended to protect persons at high risk for influenza rather than to help reduce virus transmission within the community.
- **Reactive school closures and dismissals:** These might be implemented when many students and staff members are ill and not attending school or when many students and staff members are arriving at school ill and being sent home. For example, a child care center might close because it is unable to operate under these conditions. Reactive dismissals, which might occur during outbreaks of seasonal influenza (*85*) and during pandemics (*15*), are unlikely to affect virus transmission because they typically take place after considerable, if not widespread, transmission has already occurred in the community. For example, a 4-day reactive closure in a western Kentucky school district did not reduce ILI transmission in the rural community (*86*). Similarly, closing 559 Michigan schools at least once during the fall wave (i.e., second wave) of the 2009 H1N1 pandemic had little effect on community levels of ILI (*87*).

For more information about preparing for influenza and the different types of school closures and dismissals, see CDC websites regarding 1) child care facilities (https://www.cdc.gov/h1n1flu/childcare/toolkit/pdf/childcare_toolkit.pdf), 2) K–12 schools (https://www.cdc.gov/h1n1flu/schools/toolkit/pdf/schoolflutoolkit.pdf), and 3) institutions of higher education (https://www.cdc.gov/h1n1flu/institutions/toolkit/pdf/IHE_toolkit.pdf).

Settings and use. Preemptive, coordinated school closures and dismissals might be implemented at child care facilities, K–12 schools, and institutions of higher education. They are most likely to be implemented when an influenza pandemic is severe, very severe, or extreme (Table 10). Secondary consequences include missed work and loss of income for parents who stay home from work to care for their children and missed opportunities to vaccinate school-aged children rapidly unless other mechanisms are considered.

CDC recommendations

School closures and dismissals: CDC might recommend the use of preemptive, coordinated school closures and dismissals during severe, very severe, or extreme influenza pandemics. This recommendation is in accord with the conclusions of the U.S. Community Preventive Services Task Force (https://www.thecommunityguide.org/findings/emergency-preparedness-and-response-school-dismissals-reduce-transmission-pandemic-influenza), which makes the following recommendations:

- The task force recommends preemptive, coordinated school dismissals during a severe influenza pandemic.
- The task force found insufficient evidence to recommend for or against preemptive, coordinated school dismissals during a mild or moderate influenza pandemic. In these instances, jurisdictions should make decisions that balance local benefits and potential harms.

Social Distancing Measures for Schools, Workplaces, and Mass Gatherings

Social distancing measures can reduce virus transmission by decreasing the frequency and duration of social contact among persons of all ages. These measures are common-sense approaches to limiting face-to-face contact, which reduces person-to-person transmission.

Rationale for use as a public health strategy. Social distancing measures that reduce opportunities for person-to-person virus transmission can help delay the spread and slow the exponential growth of a pandemic. The optimal strategy is to implement these measures simultaneously in places where persons gather. Although direct evidence is limited for the effectiveness of these measures, components of the strategy might include reducing social contacts at the following places:

- **Schools:** Children have higher influenza attack rates than adults, and influenza transmission is common in schools.
- **Workplaces:** More than half of all U.S. adults participate in the U.S workforce§§§ and workers often share office space and equipment and have frequent face-to-face contact. Influenza attack rates in working-age adults (aged 18–64 years) might be as high as 15.5% during a single influenza season (*88*).
- **Mass gatherings:** Group events such as concerts, festivals, and sporting events bring people into close contact for extended periods (*89–92*). A systematic literature review of respiratory disease outbreaks related to mass gatherings in the United States during 2005–2014 indicated that 40 of 72 different outbreaks were associated with state or county agriculture fairs and (zoonotic) transmission of influenza A H3N2v, and 25 outbreaks were associated with residential youth summer camps and person-to-person transmission of influenza A H1N1 (*93*). An infected traveler attending a mass gathering might introduce influenza to a previously unaffected area, and a person who becomes infected at the event can further spread the infection after returning home (*89,90,92,94–96*). Even when a circulating virus has a relatively low basic reproductive rate (R_0), intensely crowded settings might lead to high secondary attack rates (*92*). For example, during the 2013 Hajj (Islamic pilgrimage to Mecca) in Saudi Arabia, influenza A/H1N1 virus was found in only two Indonesians or Malaysians on arrival but spread to 25 persons from Africa, Central Asia, and Southeast Asia after the Hajj because of the extremely crowded conditions when performing rituals (*97*).

Multiple social distancing measures can be implemented simultaneously. Although there is limited empirical evidence supporting the effectiveness of implementing any individual measure alone (other than school closures and dismissals), the evidence for implementing multiple social distancing measures in combination with other NPIs includes systematic literature reviews, historical analyses of the 1918 pandemic, and mathematical modeling studies (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313 and supplementary Appendix 5 https://stacks.cdc.gov/view/cdc/44314).

Settings and use. Social distancing measures can be implemented in a range of community settings, including educational facilities, workplaces, and public places where people gather (e.g., parks, religious institutions, theaters, and sports arenas). The choice of social distancing measures depends on the severity of the pandemic (Table 10). Certain measures might be implemented with few secondary consequences (e.g., increased use of e-mail and teleconferences in some workplaces), whereas others might require advance planning (e.g., modification of mass gatherings). Examples of practical measures that might reduce face-to-face contact in community settings include the following:

- If schools remain open during a pandemic, divide school classes into smaller groups of students and rearrange desks so students are spaced at least 3 feet (*98*) from each other in a classroom.
- Offer telecommuting and replace in-person meetings in the workplace with video or telephone conferences.
- Modify, postpone, or cancel mass gatherings.

CDC recommendations

Social distancing measures: Even though the evidence base for the effectiveness of some of these measures is limited, CDC might recommend the simultaneous use of multiple social distancing measures to help reduce the spread of influenza in community settings (e.g., schools, workplaces, and mass gatherings) during severe, very severe, or extreme influenza pandemics while minimizing the secondary consequences of these measures. Social distancing measures include the following:

- Increasing the distance to at least 3 feet (*98*) between persons when possible might reduce person to person transmission. This applies to apparently healthy persons without symptoms. In the event of a very severe or extreme pandemic, this recommended minimal distance between people might be increased.
- Persons in community settings who show symptoms consistent with influenza and who might be infected with (probable) pandemic influenza should be separated from well persons as soon as practical, be sent home, and practice voluntary home isolation.

Environmental NPIs: Environmental Surface Cleaning Measures

Environmental surface cleaning measures can help eliminate influenza viruses from frequently touched surfaces and objects, including tables, door knobs, toys, desks, and computer keyboards. These measures involve cleaning surfaces with detergent-based cleaners or disinfectants that have been registered with the Environmental Protection Agency.¶¶¶

Rationale for use as a public health strategy. Although the percentage of influenza cases involving contact transmission (i.e., hand transfer of virus from contaminated objects to the eyes, nose, or mouth) is unknown, this mode of transmission is a recognized route of virus spread (*99*). The routine use of cleaning measures that eliminate influenza viruses from contaminated surfaces might reduce the spread of influenza viruses (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313).

Settings and use. Environmental surface cleaning measures are recommended for frequently touched surfaces and objects in homes, child care facilities, schools, workplaces, and other places where persons gather. These measures can be used for prevention of seasonal influenza and in all pandemic severity scenarios (Table 10). Use of these measures might result in some secondary consequences (e.g., failing to read instruction labels before applying disinfectants to ensure that they are safe and appropriate to use or cleaning with poor ventilation during the application process).

CDC recommendations

Environmental surface cleaning measures: CDC recommends environmental surface cleaning measures in all settings, including homes, schools, and workplaces, to remove influenza viruses from frequently touched surfaces and objects. Use of these measures might help prevent transmission of various infectious agents, including seasonal and pandemic influenza (https://www.cdc.gov/nonpharmaceutical-interventions/environmental/index.html; https://www.cdc.gov/oralhealth/infectioncontrol/questions/cleaning-disinfecting-environmental-surfaces.html).

Additional guidance is available from CDC for health care facilities (https://www.cdc.gov/hicpac/pdf/guidelines/eic_in_HCF_03.pdf), schools (https://www.cdc.gov/flu/school/cleaning.htm), and airline, travel, and transportation industries (https://www.cdc.gov/flu/pandemic-resources/archived/transportation-planning.html).

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Discussion

This report expands the NPI guidance presented in the 2007 report by providing evidence-based recommendations on the use of the same set of NPIs. These NPIs include personal protective measures for everyday use and for use during a pandemic, community measures (school closures and dismissals and social distancing), and environmental surface cleaning measures.

Key Concepts Maintained from 2007 Guidance

The rationale for and key concepts regarding the use of NPIs during influenza pandemics first presented in the 2007 guidance remain unchanged. Because production of a pandemic vaccine can take up to 6 months and antiviral medications might be prioritized for treatment, NPIs are likely to be the only prevention tools available early in a pandemic. Therefore, they are critical to slowing the spread of the pandemic influenza virus while a pandemic vaccine is under development.

Like the 2007 strategy, this 2017 update affirms the importance of prepandemic planning and preparedness for use of NPIs during a pandemic response and recommends the early, targeted, and simultaneous implementation of multiple NPIs to decrease influenza virus transmission. Although community-level NPIs can help slow virus transmission, as supported by historical information (*100*), empirical observations (*101*), and mathematical modeling (*102*), these measures are likely to cause unwanted consequences by introducing new norms for social behavior (e.g., adopting precautionary health-protective behaviors such as limiting face-to-face contact with family and friends, only shopping for essential items, avoiding places where people congregate, or not using public transportation) (*103*), interrupting routine societal functions, and entailing additional costs. If an evolving influenza pandemic is characterized by high clinical severity, the benefits of deploying NPIs, including those with greater potential for secondary consequences, are likely to outweigh potential harms. The more difficult decision is determining how and when to implement the community-level NPIs that are more disruptive to society (e.g., temporary K–12 school closures) during pandemics of moderate severity. In each locality, the goal should be to implement NPIs early enough and long enough to maximize effectiveness while minimizing economic and social costs to ensure that NPIs are commensurate to the pandemic severity.

New Elements Added in 2017

New elements in this report, in addition to the evidence-based NPI recommendations, include a summary of key lessons learned from the 2009 H1N1 pandemic response (Box 1), information on community engagement and preparedness (supplementary Chapter 1 https://stacks.cdc.gov/view/cdc/44313), and information on new or updated pandemic assessment tools (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313), which include the novel influenza virus pandemic intervals tool, the Influenza Risk Assessment Tool, and PSAF. As described in the following sections, this report also presents two additional planning tools designed to assist states and localities in ensuring pandemic preparedness.

Prepandemic Planning Scenarios for NPI Implementation According to Pandemic Severity

During the initial stages of a pandemic, CDC will use the PSAF tool to prepare an initial assessment of pandemic severity that provides early guidance on use of NPIs to help slow the transmission of the novel virus. To facilitate the use of the initial assessment information by state and local health departments, CDC has provided a set of four prepandemic planning scenarios. Each scenario aligns with one of the four assessment quadrants (Figure 3) and provides information on past influenza pandemics for comparison (Table 9). These planning scenarios are designed to facilitate state and local prepandemic planning for NPI implementation according to pandemic severity (as classified by PSAF) (Figure 6) (Tables 9 and 10). After sufficient epidemiologic data are accrued and the refined assessment of pandemic severity becomes available, CDC will issue updated pandemic NPI guidance, which will be tailored more precisely to the specific pandemic. Additional information about the planning scenarios and phasing of NPIs is available (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313).

Supplemental Prepandemic NPI Planning Guides

The 2007 report included supplemental prepandemic NPI planning guides for individuals and families; child care programs, K–12 schools, and institutions of higher education; community- and faith-based organizations; and businesses and other workplaces. These guides have been updated, and two new guides have been developed for public health communicators and event planners that address NPI communications and modification, postponement, or cancellation of mass gatherings. These guides are intended to help operationalize the 2017 update and provide specific information that can assist different groups in their prepandemic planning and decision-making (https://www.cdc.gov/nonpharmaceutical-interventions).

Future Research

Although progress has been made since 2009 toward building the evidence base for use of NPIs to slow the spread of pandemic influenza, additional research is needed. For personal NPIs, areas for additional research include evaluating the effects of increased frequency and quality of hand washing on influenza virus transmission, determining the role of infected persons who are not symptomatic in the transmission of influenza viruses in households, and assessing the effectiveness, acceptability, and feasibility of recommending face mask use by well persons in community settings as a means of avoiding infection during a pandemic. For community NPIs, one topic for additional study involves gathering empirical data on social mixing patterns in schools and community settings. These data can be used to create high-fidelity, high-resolution mathematical models of virus transmission in these settings to facilitate data-driven evaluations of different social distancing measures. Another area of research for community NPIs involves assessing the potential secondary consequences (e.g., missed work) of select community-level measures (e.g., school closures) for families, communities, and society to assess the economic effects of these measures. For environmental NPIs, additional research is needed to better understand surface contamination (e.g., which types of surfaces are more likely to be contaminated with influenza viruses) and identify situations in which surface cleaning should be emphasized (e.g., in households with confirmed influenza cases versus in healthy households). Additional information about NPI research gaps is available (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313).

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Conclusion

The 2009 H1N1 pandemic provided an opportunity to test, in practice, the key concepts of NPIs in mitigating the impact of an influenza pandemic, just 2 years after the publication of the 2007 guidance. As the experience from 2009 has shown, NPIs can be a critical component of pandemic influenza mitigation. Although well-matched pandemic vaccines remain the main tool in reducing the risk of acquiring infection and in controlling the spread of a pandemic virus, vaccines might not be widely available for up to 6 months after the emergence of a pandemic influenza virus, given current vaccine production technology. Furthermore, as during the 2009 H1N1 pandemic, antiviral medications might be prioritized for treatment but not used for widespread chemoprophylaxis because of concerns about antiviral resistance and limited stockpiles of antiviral medications. Therefore, NPIs might be the only prevention tools readily available for persons and communities to help slow transmission of an influenza virus during the initial stages of a pandemic. However, individual NPIs might be only partially effective in limiting community transmission when implemented alone. Thus, the most efficient implementation involves early, targeted, and layered use of multiple NPIs (https://www.cdc.gov/flu/pandemic-resources/planning-preparedness/community-mitigation.html). In addition, some community-level NPIs that potentially have the greatest epidemiologic effects on pandemic influenza virus transmission in communities, most notably school closures and dismissals, also are most likely to be associated with secondary (unwanted) consequences (*104*). Hence, prepandemic planning, including engaging communities in planning activities well ahead of the next pandemic, is critical to enable appropriate local decision-making during the early stages of a pandemic.

After the 2009 H1N1 pandemic, evidence on the effectiveness and feasibility of NPIs expanded substantially. A summary of the evidence in this 2017 update includes 2009 H1N1-related research (supplementary Appendix 5 https://stacks.cdc.gov/view/cdc/44314). However, knowledge gaps remain and should be addressed by future research. Further updates of these guidelines will be developed and issued when significant new information and evidence emerges about the effectiveness and feasibility of NPIs in mitigating the impact of pandemic influenza.

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Conflict of Interest

The CDC contributors wish to disclose that they have no financial or competing interests or other relationships that would unfairly influence these CDC guidelines and recommendations.

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* The updated 2017 planning guidelines do not address pandemic vaccine development and distribution, use of respirators in community or health care settings during a pandemic, or travel restrictions during a pandemic. Guidance and policies in these areas will be developed separately, as needed.

† In July 2009, ACIP recommended vaccination of several population groups, including children aged 6 months through 18 years because cases of H1N1 influenza had occurred in children who were in close contact with each other in school and child care settings (https://www.cdc.gov/h1n1flu/vaccination/acip.htm).

§ The pandemic mitigation framework proposed in the 2007 strategy was based on the early, targeted, and layered use of multiple NPIs. NPIs should be initiated early in a pandemic before local epidemics grow exponentially, be targeted toward those at the nexus of transmission (in affected areas where the novel virus circulates), and be layered together to reduce community transmission as much as possible. A list of NPIs that are recommended at all times and those that are reserved for pandemics is provided (Table 1).

¶ Influenza pandemics can range from mild to extreme in terms of rates of viral transmission and clinical severity, as described in the four prepandemic planning scenarios developed by CDC. A very severe or extreme pandemic, such as the 1918 pandemic, is characterized by high to very high transmissibility and clinical severity. A severe pandemic, such as the pandemics of 1957 and 1968, is characterized by high transmissibility and low to medium clinical severity. A mild or moderate pandemic, such as the 2009 pandemic, is characterized by low to medium transmissibility and clinical severity.

** Although many authorities use either 100°F or 100.4°F (37.8°C) as indicative of fever, this number can vary depending on factors such as the method of measurement and the age of the person. Therefore, other values for fever could be appropriate. CDC has public health recommendations that are based on the presence (or absence) of fever (i.e., persons' temperature is not higher than their own normal temperature).

†† Guidance for caring for persons at home who have influenza symptoms is available at https://www.cdc.gov/flu/consumer/caring-for-someone.htm.

§§ Additional information about isolation and quarantine is available at https://www.cdc.gov/quarantine/QuarantineIsolation.html.

¶¶ If the incubation period for the next pandemic were shorter or longer than 3 days, CDC would amend the recommendation accordingly.

*** Additional information on the use of preemptive, coordinated school closures and dismissals of different durations is available (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313).

††† Persons at high risk for influenza-related complications include children aged <5 years (and especially aged <2 years), adults aged ≥65 years, pregnant women, residents of nursing homes and other long-term care facilities, and American Indians/Alaska Natives. Those at high risk also include persons with asthma, neurological and neurodevelopmental conditions, chronic lung disease, and heart disease; disorders of the blood, endocrine system, kidney, or liver; metabolic disorders; and weakened immune systems from disease or medication. Two other groups at higher risk are persons aged <19 years who receive long-term aspirin therapy and those with extreme obesity (https://www.cdc.gov/flu/about/disease/high_risk.htm).

§§§ As of September 2016, the U.S. workforce included 62.9% of the civilian, noninstitutionalized population aged ≥16 years (**Source**: US Bureau of Labor Statistics. The employment situation—September 2016. Washington, DC: US Department of Labor; 2016. https://www.bls.gov/news.release/archives/empsit_10072016.pdf).

¶¶¶ Antimicrobial products registered for use against H1N1 influenza and other influenza A viruses on hard surfaces (https://archive.epa.gov/pesticides/oppad001/web/pdf/influenza-a-product-list.pdf).

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FIGURE 1. Goals of community mitigation for pandemic influenza

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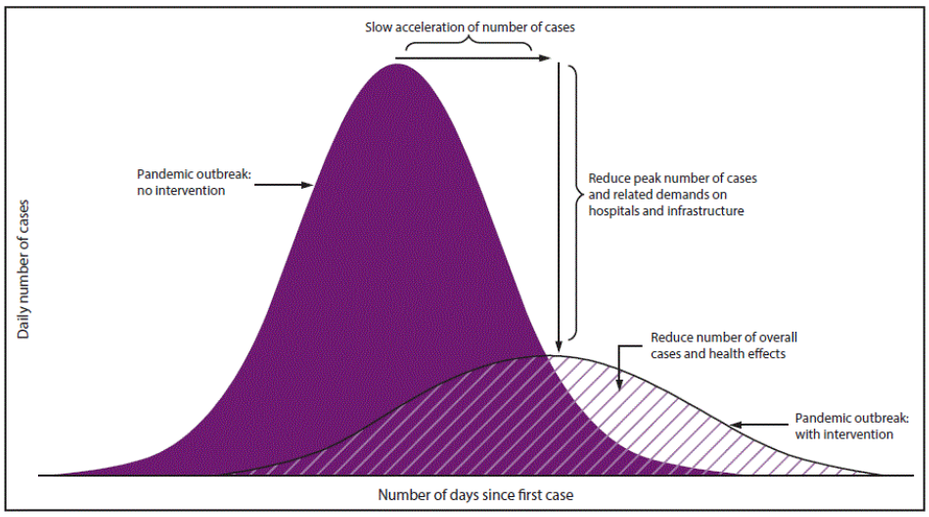

Source: Adapted from: CDC. Interim pre-pandemic planning guidance: community strategy for pandemic influenza mitigation in the United States—early, targeted, layered use of nonpharmaceutical interventions. Atlanta, GA: US Department of Health and Human Services, CDC; 2007. https://stacks.cdc.gov/view/cdc/11425.

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TABLE 1. Nonpharmaceutical interventions for personal and community preparedness to prevent pandemic influenza

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NPI category*	NPIs	Timing
Personal		
Personal protective measures for everyday use	Voluntary home isolation of ill persons (staying home when ill)	Recommended at all times
	Respiratory etiquette	
	Hand hygiene	

Personal protective measures reserved for pandemics	Voluntary home quarantine of exposed household members (staying home for up to 3 days[†] when a household member is ill)	Reserved for pandemics
	Use of face masks in community settings when ill	
Community		
School closures and dismissals[§]	Temporary, preemptive, coordinated dismissals of child care facilities and schools for grades K–12[¶]	Reserved for pandemics
Social distancing measures (examples)	Dividing classes into smaller groups and creating opportunities for distance learning (e.g., via the internet or local television or radio stations)	Reserved for pandemics
	Telecommuting and remote-meeting options in workplaces	
	Mass gathering modifications, postponements, or cancellations	
Environmental		
Environmental surface cleaning measures	Routine cleaning of frequently touched surfaces and objects in homes, child care facilities, schools, and workplaces	Recommended at all times

Abbreviation: NPI = nonpharmaceutical intervention.
*Personal, community, and environmental NPIs should be 1) initiated early in a pandemic before local epidemics begin to grow exponentially, 2) targeted toward the nexus of transmission (in affected areas where the novel virus circulates), and 3) layered together to reduce community transmission to the greatest extent possible.
[†]If the incubation period for the next pandemic influenza virus is longer or shorter than 3 days, CDC will amend the recommendation.
[§]A school closure involves closing a school and sending all the students and staff members home. A school dismissal could involve a school staying open for staff members while the students stay home.
[¶]Preemptive, coordinated dismissals might be implemented early during a pandemic to decrease the spread of influenza before many students and staff members become ill. Selective dismissals might be implemented by schools that serve students at high risk for complications from infection with influenza. Reactive dismissals might be implemented when many students and staff members are ill and not attending school or when many students and staff members are arriving at school ill and being sent home. Selective and reactive dismissals do not help slow disease transmission in the community.

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TABLE 2. Factors to consider before implementing nonpharmaceutical interventions during an influenza pandemic

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Planning factors	Planning goals	Activities
Ethical considerations	• Community engagement in prepandemic planning • Equitable distribution of public health resources during a pandemic	• Promoting public input into NPI planning • Ensuring that NPIs benefit all groups within a community • Carefully considering and justifying any restrictions on individual freedom needed to implement NPIs (e.g., voluntary home quarantine of exposed household members)

Feasibility of NPI implementation	• Minimal interruption of regular programs and activities
	• Selection of NPIs that are practical to implement within each community
		• Identifying practical obstacles to NPI implementation and considering ways to overcome them. Examples include the following:
		  ○ Educational issues (e.g., missed educational opportunities or loss of free or subsidized school meals because of school dismissals)
		  ○ Financial issues (e.g., workers who cannot afford to stay home when they are ill or to care for an ill family member because they do not have paid sick leave)
		  ○ Legal issues (e.g., local jurisdictions that do not have the legal authority to close schools or cancel mass gatherings for public health reasons)
		  ○ Workplace issues (e.g., access to clean water, soap, or hand sanitizer and flexible workplace policies or arrangements)

Activation triggers, layering, and duration of NPIs	• Optimal implementation of NPIs during a pandemic	• Maximizing the effectiveness of NPIs by taking the following actions:
		  ○ Identifying activation triggers to ensure early implementation of NPIs before explosive growth of the pandemic
		  ○ Planning for simultaneous use of multiple NPIs because each NPI is only partially effective
		  ○ Planning for long-term duration of school dismissals and social distancing measures

Selecting NPIs for groups at risk for severe influenza complications and for those with limited access to care and services	• Protection of persons most at risk for severe illness or death during a pandemic
	• Protection of persons who might need additional assistance during a pandemic response, including persons with disabilities and other access and functional needs
		• Identifying strategies for implementing NPIs among groups at high risk for severe influenza-related complications, including the following:
		  ○ Pregnant women
		  ○ Persons aged <5 yrs and ≥65 yrs
		  ○ Persons with underlying chronic diseases
		  ○ Persons in institutions
		• Identifying strategies for implementing NPIs among groups who might experience barriers to or difficulties with accessing or receiving medical care and services, including the following:
		  ○ Persons who are culturally, geographically, or socially isolated or economically disadvantaged
		  ○ Persons with physical disabilities, limitations, or impairments
		  ○ Persons with low incomes, single-parent families, and residents of public housing
		  ○ Persons who live in medically underserved communities

Public acceptance of NPIs	• Active participation in NPI implementation during a pandemic	• Promoting public understanding that individual action is essential for effective implementation of NPIs in every pandemic scenario. In many scenarios, both personal and community NPIs might be recommended. NPI recommendations might change as new knowledge is gained. • Identifying key personnel to disseminate emergency information (e.g., alerts, warnings, and notifications) and establishing communication channels that enable members of the public to ask questions and express concerns (e.g., call centers or social media sites) • Ensuring that school dismissals and other NPIs are acceptable to the community during a pandemic • Coordinating with local partners to support households complying with voluntary home quarantine (e.g., providing necessary food and supplies) • Identifying strategies for mitigating the secondary consequences of school dismissals and other social distancing measures (e.g., modifications or cancellations of mass gatherings) • Minimizing intervention fatigue* during a pandemic
Balancing public health benefits and social costs	• Maximization of NPI public health benefits and minimization of social and economic costs during a pandemic	• Estimating economic and social costs of NPIs and their secondary (unintended or unwanted) consequences • Balancing those costs against public health benefits, with reference to different prepandemic planning scenarios • Identifying strategies for reducing the cost of NPI implementation

Monitoring and evaluation of NPIs	• Ongoing guidance during a pandemic on optimal NPI implementation, maintenance, and discontinuation	• Identifying ways to monitor and evaluate the following:
		  ○ Degree of transmission and severity of the evolving pandemic
		  ○ Type and degree of NPI implementation
		  ○ Level of compliance with NPI measures and the emergence of intervention fatigue
		  ○ Effectiveness of NPIs in mitigating pandemic impact
		  ○ Secondary consequences of NPIs and the effectiveness of strategies to mitigate them

Abbreviation: NPI = nonpharmaceutical intervention.
Source: Adapted from: Barrios LC, Koonin LM, Kohl KS, Cetron M. Selecting nonpharmaceutical strategies to minimize influenza spread: the 2009 influenza A (H1N1) pandemic and beyond. Public Health Rep 2012;127:565–71.

*Fatigue that results from being requested, often repeatedly, mmunity, especially when those changes disrupt daily life (e.g., caring for children when schools are dismissed for several weeks or avoiding crowded settings) (**Source:** Ryan JR, ed. Pandemic influenza: emergency planning and community preparedness. 2008. Boca Raton, FL: CRC Press; 2008:158).

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TABLE 3. Examples of possible nonpharmaceutical intervention surveillance indicators for an influenza pandemic

Key influenza indicator	U.S. data source	Measure of influenza activity
Indicators of spread or level of influenza activity		
Percentage of patient visits to health care providers for ILI in the United States	Outpatient ILI Surveillance Network (ILINet), which includes approximately 2,900 enrolled outpatient health care providers in 50 states	Current ILI level in relation to most recent national and region-specific baseline levels, with CDC providing baseline values for the 10 HHS surveillance regions and for the United States as a whole https://www.cdc.gov/flu/weekly/overview.htm
ILI activity by state: percentage of outpatient visits for ILI in a state (ranges from minimal to high)	Outpatient ILI Surveillance Network (ILINet) Additional: Flu Near You https://flunearyou.org/	Ten activity levels that compare the mean reported percent of visits due to ILI for the current week to noninfluenza weeks, specifying the number of standard deviations at or above the mean for the current week https://www.cdc.gov/flu/weekly/FluViewInteractive.htm
Geographic spread of influenza in a state (ranges from none to widespread)	State and Territorial Epidemiologists reports	Estimated weekly levels of geographic spread (local, regional, or widespread) of influenza activity reported by state health departments https://www.cdc.gov/flu/weekly/overview.htm
Percentage of respiratory specimens that test positive for influenza viruses in the United States	Approximately 110 U.S. WHO collaborating laboratories and 240 National Respiratory and Enteric Virus Surveillance System laboratories	National and regional percentage of respiratory specimens testing positive for influenza viruses https://www.cdc.gov/flu/weekly/FluViewInteractive.htm
Absenteeism rates due to ILI in child care facilities, K–12 schools, or colleges and universities (reflects number of ILI cases)	ILI monitoring/surveillance systems in child care facilities, K–12 schools, or colleges and universities	Increased absenteeism rates due to ILI in child care facilities, K-12 schools, or colleges and universities (reflects increased number of ILI cases)
Laboratory-confirmed influenza cases among students, teachers, and staff members		Increases in laboratory-confirmed influenza cases among students, teachers, and staff members
		Laboratory-confirmed outbreaks of influenza in child care facilities, K–12 schools, or colleges and universities
Indicators of clinical severity of influenza		
Influenza-associated hospitalizations	Influenza Hospitalization Surveillance Network (FluSurv-NET), which collects data from the 10 Emerging Infections Program sites, as well as Michigan, Ohio, and Utah (https://wwwnc.cdc.gov/eid/article/21/9/14-1912_article)	Population-based rate of influenza-associated hospitalizations in multiple geographic areas https://www.cdc.gov/flu/weekly/FluViewInteractive.htm
Percentage of deaths attributed to pneumonia and influenza	National Center for Health Statistics mortality surveillance system	The percentage of death certificates indicating pneumonia and influenza compared with a seasonal baseline and epidemic threshold value calculated for each week (using a periodic regression model) https://www.cdc.gov/flu/weekly
Influenza-associated deaths among persons aged <18 yrs	Influenza-Associated Pediatric Mortality Surveillance System	Any laboratory-confirmed influenza-associated deaths in children, all of which are reported through this system https://www.cdc.gov/flu/weekly/FluViewInteractive.htm

Abbreviations: HHS = U.S. Department of Health and Human Services; ILI = influenza-like illness; WHO = World Health Organization.

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BOX 1. Lessons learned from the 2009 H1N1 pandemic response

The 2009 H1N1 pandemic demonstrated the unpredictable nature of influenza viruses and showed that prepandemic planning must be broad and flexible. Lessons learned during the 2009 H1N1 pandemic response from the United States and other affected countries follow.

H1N1 and children

The epidemiology of pandemic influenza might be different from the epidemiology of seasonal influenza; therefore, different populations might be disproportionately affected.

- An estimated 43–89 million people in the United States were infected with H1N1pdm09 virus during April 2009–April 2010, and approximately 12,000 people died (*3*).
- Severe outcomes of influenza include complications that require hospitalization and can be fatal (e.g., pneumonia or bronchitis). Severe outcomes from H1N1pdm09 virus infection were most common among children, young adults, and specific groups at high risk for complications (e.g., pregnant women) rather than in adults aged ≥65 years, the group most at risk from seasonal influenza (*4–7*). Over the course of the pandemic, an estimated 86,000 children were hospitalized in the United States, which is 2–3 times the number admitted during a typical influenza season (*5*). The number of deaths among children also was more than twice as high as during a regular influenza season.
- On August 28, 2009, the Advisory Committee on Immunization Practices recommended that children be placed higher on the priority list for receiving the monovalent H1N1 vaccine, which became available in October 2009 (*8*).
- Children at risk for severe outcomes from the H1N1pdm09 virus (and from any influenza virus) included those with underlying health conditions such as asthma, diabetes, obesity, or heart, lung, or neurologic diseases. Approximately 60% of hospitalized children had one or more of these conditions, compared with 80% of hospitalized adults (*5*). Infants born to mothers infected with the H1N1pdm09 virus also might have been at risk, as suggested by U.S. and Canadian studies which found that infants whose mothers received the H1N1 vaccine were less likely to be small for their gestational age or delivered preterm (*9,10*).

Public health tools to assess pandemic severity and guide NPI selection

The 2007 Pandemic Severity Index had limited usefulness because attack rates and case-fatality ratios were difficult to measure and imprecise early in the pandemic.

- The earliest available data on attack rates and case-fatality ratios suggested that the 2009 H1N1 pandemic virus was highly transmissible and caused severe outcomes. However, the cases being reported overestimated severity because they were primarily derived from mortality data.
- By May 1, 2009, which was 5 days after the U.S. Department of Health and Human Services (HHS) declared a nationwide public health emergency, CDC had received reports of 141 laboratory-confirmed H1N1pdm09 cases in 19 states, with one death in Texas (https://www.cdc.gov/h1n1flu/updates/050109.htm). On the basis of this initial information and continued reports of cases of disease with severe outcomes in Mexico, including deaths among previously healthy young adults (*11*), CDC recommended that communities with laboratory-confirmed cases of H1N1pdm09 virus consider closing child care facilities and schools, depending on the extent and severity of illness (*12*). CDC also recommended other NPIs described in the 2007 strategy, including voluntary home isolation for ill persons (i.e., staying home when ill) and voluntary home quarantine for exposed household members (i.e., staying home when a household member is ill).
- Within 12 days of recognition of the emerging pandemic, the national influenza surveillance system generated sufficient data for a refined assessment.
  - From April 23, 2009, when H1N1pdm09 virus was detected in California (*13*), through May 5, 2009, CDC received reports of 403 confirmed cases of H1N1pdm09 virus in 38 states. The low rates of hospitalizations and deaths, as well as reported attack rates similar to those for seasonal influenza, suggested that the majority of U.S. cases were less severe than those reported from Mexico.
  - CDC issued new nonpharmaceutical intervention (NPI) guidance on May 5, 2009 (*14*), recommending that although ill students and teachers should stay home, schools did not need to close. The guidance acknowledged that public health authorities in certain jurisdictions might still decide to close schools on the basis of local considerations, including public concern, school absenteeism, and staffing shortages.
  - During August–December 2009, communities in 46 U.S. states implemented 812 dismissal events (i.e., a single school dismissal or dismissal of all schools in a district), affecting 1,947 schools with approximately 623,616 students and 40,521 teachers (*15*). The 1,947 schools included 639 urban and 1,250 rural schools, representing 0.7% and 3.3% of all urban and rural schools, respectively, in the United States.
- The recognition that the Pandemic Severity Index was of limited use during the earliest stages of an actual pandemic led to the development of a new tool for evaluating the potential effects of an emerging pandemic, the Pandemic Severity Assessment Framework (PSAF) (supplementary Chapter 2 https://stacks.cdc.gov/view/cdc/44313).

NPIs and influenza transmission

Well-established methods to prevent seasonal influenza transmission, such as hand hygiene promotion, also were effective in pandemic influenza settings to prevent the spread of H1N1pdm09 virus in some communities.

- **Hand hygiene.** A randomized trial, conducted over 12 weeks in 60 elementary schools in Cairo, Egypt, during the 2009 H1N1 pandemic, demonstrated a 47% reduction in confirmed cases of influenza after twice-daily hand washing and health hygiene instruction in comparison with a control group that did not receive health hygiene instruction or have access to soap and hand-drying materials (*16*). This study demonstrated the effects of hand washing on laboratory-confirmed influenza in a population of persons that typically have little or no access to soap or hand-drying materials and among whom frequent hand washing is not standard.
- **School closures and dismissals.** Data from the United States, Canada, and Mexico suggest that early implementation of school closures and dismissals reduced the spread of H1N1pdm09 virus.
  - Two waves of the 2009 H1N1 pandemic occurred in the United States, one in spring 2009 and one in fall 2009. The majority of pandemic cases occurred during the fall wave (*4*), as H1N1pdm09 cases surged in many U.S. communities about 2 weeks after schools reopened after summer break. Opening dates for schools ranged from early August through early September (*17*). A comparison of Texas school districts that closed versus those that stayed open during the pandemic found that school closure was associated with a 45%–72% reduction in acute respiratory illness in households with school-aged children (*18*).
  - Mathematical models suggested that school closures in Alberta, Canada, in May 2009 were associated with reduced transmission among school children by approximately 50%, attenuating the first wave of the 2009 H1N1 epidemic (*19*).
  - H1N1pdm09 virus transmission in the greater Mexico City, Mexico, area decreased by an estimated 29%–37% after school closures and implementation of other social distancing measures (*20*).
  - After conducting a systematic review of scientific literature published through February 2011, including initial data gathered during the 2009 H1N1 pandemic, the U.S. Community Preventive Services Task Force found insufficient evidence to determine whether the public health benefits of preemptive, coordinated school dismissals balanced their economic and social costs during a mild or moderate influenza pandemic. However, the task force did recommend preemptive, coordinated school dismissals during a severe pandemic (*21*).
- **Social distancing measures.** H1N1pdm09 virus transmission in Mexico decreased significantly after school closures and implementation of other social distancing measures (*20,22*). In the United States, schools in Georgia that shortened school days had less absenteeism due to severe respiratory illness (*23*).

Additional assessments are needed to determine the value of combining voluntary home quarantine with antiviral chemoprophylaxis.

- Although the 2007 strategy suggested that communities consider combining voluntary home quarantine with prophylactic use of antiviral medications, assuming a feasible means of distribution, HHS did not adopt antiviral chemoprophylaxis as its official policy because of concerns about insufficient supplies and drug resistance.
- During the 2009 H1N1 pandemic, antiviral chemoprophylaxis of exposed persons contained the spread of the disease, along with the implementation of social distancing measures, in a few small, well-defined settings, including a summer camp (*24*) and a cruise ship (*25*). Moreover, an observational cohort study of 259 households in the United Kingdom found that administration of antiviral medications to 285 confirmed patients and their 761 close contacts was very effective (92%) in preventing household transmission (*26*).
- Although limited, the H1N1pdm09 experience suggests that antiviral chemoprophylaxis might be recommended in the future in some settings as an adjunct to self-quarantine, assuming that additional antiviral medications are on the market, providing more treatment choices and making the emergence of drug resistance less of a concern. However, this recommendation would require much greater quantities of antiviral medications, even if no new products are developed, to ensure sufficient supplies.

Mobilizing the public

Most members of the public complied with public health recommendations regarding hand hygiene and social distancing.

- The Harvard Opinion Research Program conducted 13 polls on the response of the U.S. public during the 2009–2010 pandemic, including the response of the general public, pregnant women, new mothers, parents, and businesses. These randomized telephone polls found the following:
  - A total of 59% of 1,067 Americans reported washing their hands or using hand sanitizer more frequently during the 2009 H1N1 pandemic (*27*). A total of 25% avoided places where numerous people tend to gather, such as sporting events, malls, or public transportation.
  - Most (85%) of 514 pregnant women washed or sanitized their hands more frequently to reduce the chance of infection with H1N1pdm09 virus (*27*). A total of 68% reported taking steps to avoid proximity to someone who had influenza-like symptoms, and 31% avoided mass gatherings places. Most (91%) of 526 new mothers also washed or sanitized their hands more frequently, and 81% took steps to avoid being near someone who had influenza-like symptoms.

School-related NPIs, including school closures and dismissals, were acceptable and feasible.

- According to a Harvard Opinion Research Program poll of 523 parents from 39 U.S. states whose child care center or school closed temporarily in response to the 2009 H1N1 pandemic, 90% of parents agreed with the dismissal decision, and 85% believed the dismissal reduced influenza transmission (*27,28*).
  - A total of 75% of parents who responded stated that the dismissal was not a problem, and 3% stated it was a major problem. Approximately 20% of parents reported that an adult in the household missed work because of the dismissal, and 19% had a child who missed a free or reduced-cost lunch. Of these, 2% and <1%, respectively, said missing work and missing lunch were major problems.
  - Most of the 523 parents polled believed that at least one of the following factors was a major reason the institution had closed: 1) to keep children apart and reduce the chance they would infect each other (81%), 2) because the school decided cleaning the building and surfaces that children touch was important for reducing the spread of the illness (73%), and 3) because the school or child care center could not operate effectively when numerous students were absent (58%).
- A study conducted through an online survey of school principals showed that implementing NPIs in public schools in New York City, New York, was feasible during the 2009 H1N1 pandemic (*29*). Schools successfully implemented respiratory etiquette education, hand-hygiene measures, and environmental measures and isolated ill students. Another online survey found that the majority of public schools in Georgia also were able to successfully implement both personal and community NPIs recommended by CDC (*23*).

Public health practitioners should be prepared to explain that the initial pandemic guidance might change if a pandemic is more or less severe than initially assessed.

- Within 12 days of recognizing the emerging pandemic on April 23, 2009, CDC updated its initial guidance on NPIs (issued on May 1, 2009) on May 5, 2009, on the basis of more complete and robust data that suggested that the majority of U.S. cases were less severe than those reported from Mexico.
- Certain public health departments reported difficulties in communicating the updated guidance on school closures to their communities, especially communities that were planning to implement school closures or had already done so (*30,31*).
- The H1N1pdm09 experience with school closures suggests the need to coordinate and harmonize school closure policies across jurisdictions and to proactively communicate and explain any jurisdictional differences.

Public engagement, community preparedness, and trust in government action are important for successful NPI implementation during a pandemic.

- Practical obstacles to NPI implementation that required community-level solutions included 1) ill persons going to work because they lacked unpaid leave (*32*), 2) lack of clarity about decision-making authority to close schools for public health reasons in some jurisdictions (*30,33*), and 3) lack of access to clean water, soap, or hand sanitizer in some workplaces.
- Although 74% of 1,057 businesses that participated in a Harvard Opinion Research Program poll on business preparedness for the H1N1pdm09 virus offered paid sick leave for at least some workers (*27*), fewer offered paid leave that would allow workers to take care of ill family members (35%) or to take time off to care for children if schools or child care centers closed (21%).
- In large cities such as New York City, New York, rapid implementation of local-level response strategies required advanced planning and preparation, as well as high-level political leadership; collaboration between public health and emergency management agencies; coordination with businesses, nongovernmental organizations, and community- and faith-based organizations; and transparent communication with the public (*34*).
- During future pandemics, local health policies and risk communication strategies should take into account community attitudes and acceptance of preventive behaviors related to social distancing, hand hygiene, and vaccination, which might differ across racial and economic groups (*35*).
- According to an online survey of a nationally representative sample conducted by the University of Maryland, clear and consistent communication by public health authorities and government spokespersons, including the use of role models, was important to the public's trust in government actions during the 2009 H1N1 pandemic (*36*). Although the University of Maryland study focused on risk communications related to H1N1 vaccination, this finding also is likely to apply to public attitudes about NPI implementation.

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BOX 2. Principles of community engagement

Planning

Before initiating a community engagement effort, consider the following:

1. Be clear about the purpose or goals of the engagement effort and the relevant populations and communities.

2. Become knowledgeable about the community's culture, economic conditions, social networks, political and power structures, norms and values, demographic trends, history, and experience with efforts by outside groups to engage it in various programs. Learn about the community's perceptions of those initiating the engagement activities.

Initiation

For engagement to occur, the following steps are necessary:

3. Go to the community, establish relationships, build trust, work with the formal and informal leaders, and seek commitment from community organizations and leaders to create processes for mobilizing the community.

4. Remember and accept that collective self-determination is the responsibility and right of all people in a community. No external entity should assume the ability to bestow on a community the power to act in its own self-interest.

Implementation

For engagement to succeed, consider the following:

5. Partnering with the community is necessary to create change and improve health.

6. All aspects of community engagement must recognize and respect the diversity of the community. Awareness of the various cultures of a community and other factors affecting diversity must be paramount in planning, designing, and implementing approaches to engaging a community.

7. Community engagement can only be sustained by identifying and mobilizing community assets and strengths and by developing the community's capacity and resources to make decisions and take action.

8. Organizations that would like to involve a community and those seeking to effect change must be prepared to release control of actions or interventions to the community and be flexible enough to meet changing needs.

9. Community collaboration requires long-term commitment by the engaging organization and its partners.

Source: Adapted from: Agency for Toxic Substances and Disease Registry. Principles of community engagement. Atlanta, GA: CDC, Agency for Toxic Substances and Disease Registry. https://www.atsdr.cdc.gov/communityengagement/pdf/PCE_Report_Chapter_2_SHEF.pdf

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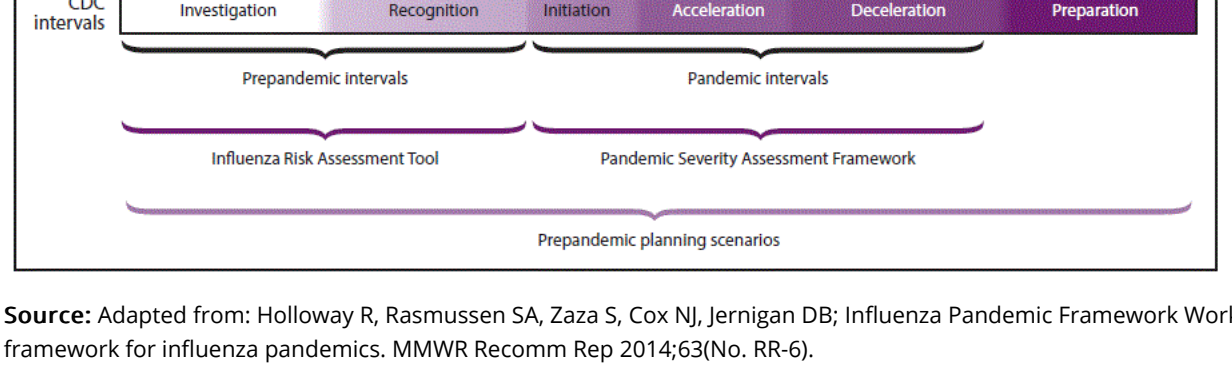
FIGURE 2. Preparedness and response framework for novel influenza A virus pandemics, with CDC intervals and World Health Organization phases



Source: Adapted from: Holloway R, Rasmussen SA, Zaza S, Cox NJ, Jernigan DB; Influenza Pandemic Framework Workgroup. Updated preparedness and response framework for influenza pandemics. MMWR Recomm Rep 2014;63(No. RR-6).

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TABLE 4. CDC novel influenza virus pandemic intervals

Intervals	Indicators
Investigation: Investigation of novel influenza cases	This interval is indicated by the identification of an animal case of influenza A subtype with potential implications for human health or identification of a human case of novel influenza A anywhere in the world.
Recognition: Recognition of potential for ongoing transmission	This interval is indicated by an increasing number of cases or clusters of novel influenza A in humans and by virus characteristics indicating potential for ongoing human-to-human transmission anywhere in the world.
Initiation: Initiation of the pandemic wave	This interval is indicated by confirmation of cases of novel influenza A in humans and demonstration of efficient and sustained human-to-human transmission anywhere in the world.
Acceleration: Acceleration of the pandemic wave	This interval is indicated by an increasing rate of novel influenza A cases identified nationally, indicating establishment in the country.
Deceleration: Deceleration of the pandemic wave	This interval is indicated by decreasing rates of novel influenza A infection.
Preparation: Preparation for a future pandemic wave	This interval is indicated by sporadic cases of novel influenza A infection and surveillance rates returning to baseline.

Source: Holloway R, Rasmussen SA, Zaza S, Cox NJ, Jernigan DB; Influenza Pandemic Framework Workgroup. Updated preparedness and response framework for influenza pandemics. MMWR Recomm Rep 2014;63(No. RR-6).

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TABLE 5. Initial assessment: scaled measures of influenza virus transmissibility and clinical severity

	Scale	
Measures of transmissibility and clinical severity	**Low to moderate**	**Moderate to high**
Transmissibility		
Secondary attack rate, household	≤20%	>20%
Attack rate, school or university	≤30%	>30%
Attack rate, workplace or community	≤20%	>20%
R^0: basic reproductive number	1–1.7	≥1.8
Underlying population immunity	Some underlying population immunity	Little to no underlying population immunity
Emergency department or other outpatient visits for influenza-like illness	<10%	≥10%
Virologic characterization	Genetic markers for transmissibility absent	Genetic markers for transmissibility present
Animal models, transmission studies	Less efficient or similar to seasonal influenza	More efficient than seasonal influenza
Clinical severity		
Upper bound of case-fatality ratio	<1%	≥1%
Upper bound of case-hospitalization ratio	<10%	≥10%
Deaths-hospitalizations ratio	<10%	≥10%
Virologic characterization	Genetic markers for virulence absent	Genetic markers for virulence present
Animal models, evaluation of morbidity and mortality	Less virulent or similar to seasonal influenza	More virulent than seasonal influenza

Source: Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91.

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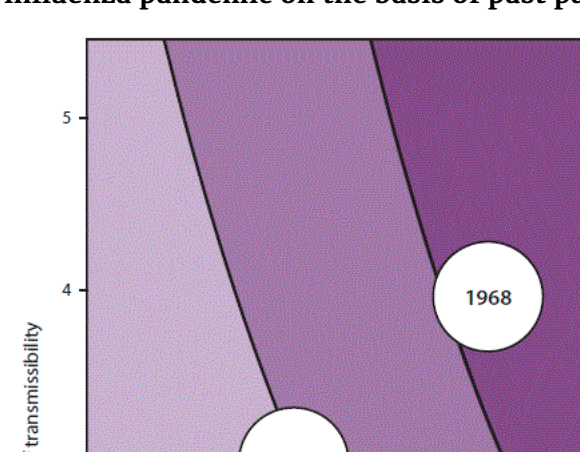
FIGURE 3. Pandemic Severity Assessment Framework for the initial assessment of the potential impact of an influenza pandemic



Source: Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91.

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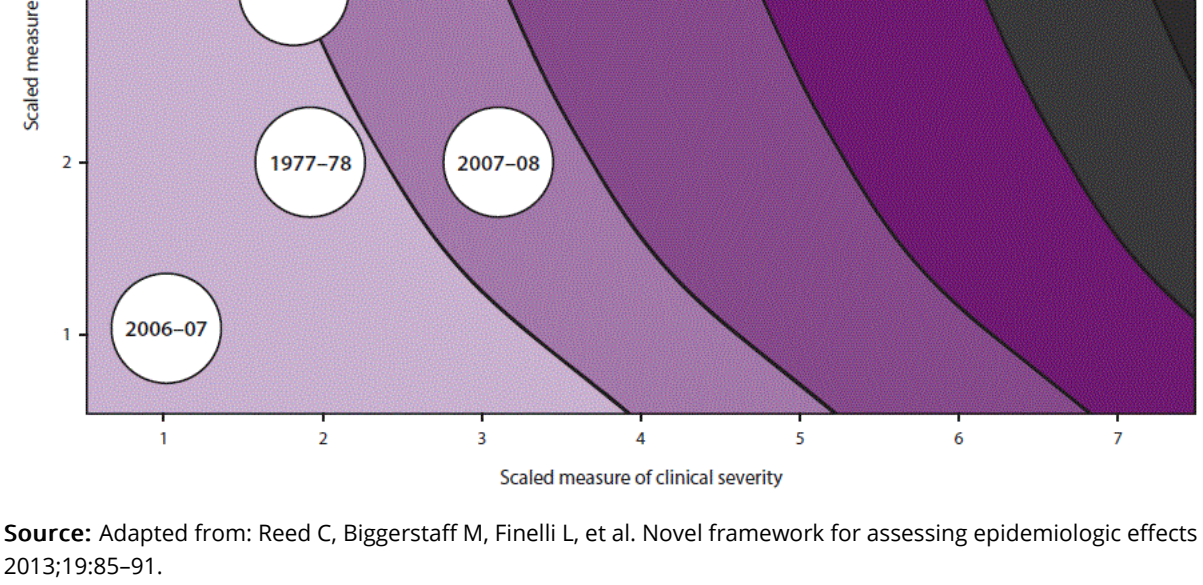
FIGURE 4. Pandemic Severity Assessment Framework using surveillance indicators for the refined assessment* of an influenza pandemic on the basis of past pandemics and influenza seasons



Source: Adapted from: Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91.

* Colors transition from light to dark as the estimated number of deaths increases. Transmissibility: measured on a scale of 1–5 and includes school, workplace, and community attack rates, secondary household attack rates, school and/or workplace absenteeism rates, and rates of emergency department and outpatient visits for influenza-like illness. Clinical severity: measured on a scale of 1–7 and includes case-fatality ratios, case-hospitalization ratios, and deaths-hospitalizations ratios.

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TABLE 6. Refined assessment: scaled measures of influenza virus transmissibility and clinical severity

	Scale						
Measures of transmissibility and clinical severity	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Transmissibility (scale of 1–5)							
Symptomatic attack rate, community	≤10%	11%–15%	16%–20%	21%–24%	≥25%	—	—
Symptomatic attack rate, school	≤20%	21%–25%	26%–30%	31%–35%	≥36%	—	—
Symptomatic attack rate, workplace	≤10%	11%–15%	16%–20%	21%–24%	≥25%	—	—
Household secondary attack rate, symptomatic	≤5%	6%–10%	11%–15%	16%–20%	≥21%	—	—
R^0: basic reproductive number	≤1.1	1.2–1.3	1.4–1.5	1.6–1.7	≥1.8	—	—
Peak percentage of outpatient visits for influenza-like illness	1%–3%	4%–6%	7%–9%	10%–12%	≥13%	—	—
Clinical severity (scale of 1–7)							
Case-fatality ratio	<0.02%	0.02%–0.05%	0.05%–0.1%	0.1%–0.25%	0.25%–0.5%	0.5%–1%	>1%
Case-hospitalization ratio	<0.5%	0.5%–0.8%	0.8%–1.5%	1.5%–3%	3%–5%	5%–7%	>7%
Deaths-hospitalizations ratio	≤3%	4%–6%	7%–9%	10%–12%	13%–15%	16%–18%	>18%

Source: Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91.

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TABLE 7. Process for developing the community mitigation guidelines for pandemic influenza, October 2011–October 2016

Topic	Comment
Goal of the guidelines	The goal of the 2017 guidelines is to update the 2007 guidance and provide updated recommendations on the use of NPIs during an influenza pandemic in the United States, based on lessons learned from the 2009 H1N1 pandemic and on an expanded evidence base for NPIs that includes studies conducted since 2007.
Users of the guidelines	State, tribal, local, and territorial public health authorities
Population and settings	The updated 2017 planning guidelines apply but are not limited to activities conducted by public health authorities who are responsible for facilitating and implementing emergency preparedness, planning, and response efforts in community settings (e.g., schools, workplaces, and mass gatherings).
Developer of the guidelines	The CDC Community Mitigation Guidelines Work Group convened in October 2012. The group is composed of staff from CDC's Office of Infectious Diseases, Influenza Coordination Unit, National Center for Emerging and Zoonotic Infectious Diseases, and National Center for Immunization and Respiratory Diseases. The work group members are subject-matter experts in seasonal and pandemic influenza, community mitigation measures, NPIs, epidemiology, health policy, and technical guidelines development. The work group provided technical oversight, coordinated the guidelines development process, and contributed to the writing of the updated guidelines.
Development of the guidelines	The updated planning guidelines are based on a NPI report developed beginning in October 2011 and finalized in August 2013. The NPI report was developed for internal CDC discussions and served as the foundation for updating the NPI recommendations from the 2007 guidance.
Evidence collection	The NPI recommendations in the 2017 guidelines are based on studies published in English-language, peer-reviewed journals through September 2016. The evidence base for NPIs includes systematic literature reviews, metaanalyses, and evidence from epidemiologic studies, laboratory experiments, and modeling simulations.
Method for data synthesis	Staff members from CDC's Community Interventions for Infection Control Unit worked in pairs to ensure quality control. They reviewed, abstracted, synthesized, and entered approximately 191 articles into spreadsheets to help establish the overall NPI body of literature, including the evidence base for NPIs.
Development of the recommendations	The approach used by the *Guide to Community Preventive Services* (*The Community Guide*) was adapted and applied to develop the NPI recommendations in the updated planning guidelines.
Planning guides	To help operationalize the updated guidelines, six community mitigation prepandemic planning guides have been developed for key populations and decision-makers in community settings. During September–October 2015, before submission for CDC clearance, the National Public Health Information Coalition facilitated discussion of the planning guides by representatives of the public health, education, and business communities. The guides are part of a set of practical, user-friendly, and plain-language companion implementation materials.
Updating the guidelines	The 2017 guidelines will be updated when new information warrants their modification.

Abbreviation: NPI = nonpharmaceutical intervention.

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TABLE 8. Number of selected peer-reviewed articles on nonpharmaceutical interventions used to develop community mitigation guidelines for pandemic influenza, by NPI type and measure and by article topic

	Number and type of articles reviewed*		
NPI type and measure	**Background**	**Evidence based**[†]	**Implementation issues**
Personal NPIs			
Personal protective measures for everyday use			
Voluntary home isolation[§]	2	7	1
Respiratory etiquette	2	0	3
Hand hygiene	3	15	11
Personal protective measures reserved for pandemics			
Voluntary home quarantine[§]	1	0	3
Use of face masks in community settings	0	18	4
Community NPIs			
School closures and dismissals	24	25	26
Social distancing measures for schools, workplaces, and mass gatherings	10	12	11
Environmental NPIs			
Environmental surface cleaning measures	1	12	0

Abbreviation: NPI = nonpharmaceutical intervention.

*Articles that are cited in more than one section in the supplementary document (supplementary Chapter 3 https://stacks.cdc.gov/view/cdc/44313) are not counted twice in this table.

[†]Of the 89 evidence-based articles, 27 articles assessed the effectiveness of NPIs when used in combination with one another. The evidence-based articles include 14 systematic literature reviews and metaanalyses composed of approximately 475 individual studies that were reviewed and analyzed by their respective authors. These studies contribute to the overall body of literature on NPIs and help support the evidence base on the effectiveness of NPIs. They are provided (supplementary Appendix 6 https://stacks.cdc.gov/view/cdc/44313) but are not accounted for in this table because CDC staff members did not re-review them.

[§]Voluntary home isolation and voluntary home quarantine share the same set of evidence-based articles.

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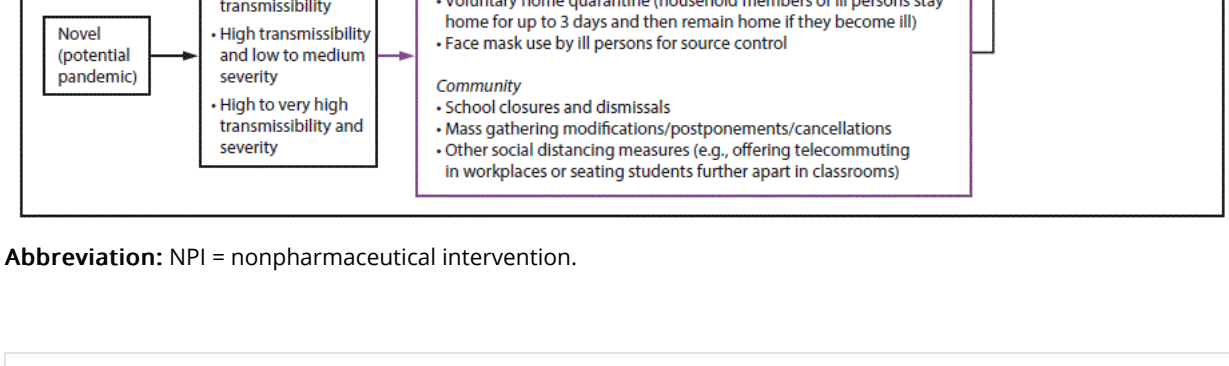
FIGURE 5. Phased addition of nonpharmaceutical interventions to prevent the spread of pandemic influenza in communities



Abbreviation: NPI = nonpharmaceutical intervention.

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TABLE 9. Prepandemic influenza planning scenarios to guide implementation of nonpharmaceutical interventions, by severity of pandemic and the Pandemic Severity Assessment Framework quadrant

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Severity of pandemic and PSAF quadrant	Implications of clinical severity and transmissibility in this scenario*	Possible no. of hospitalizations and deaths if unmitigated,† by age group: Age groups (yrs)	No. of hospitalizations	No. of deaths	Historical experience
Low to moderate severity (mild to moderate pandemic) PSAF quadrant: A	• Clinical severity and transmissibility similar to the range seen during annual influenza seasons. • Estimated overall attack and case-fatality rates: 18% and 0.03%, respectively. Rates of severe outcomes are greater among younger persons than during influenza seasons.	**All ages**	**340,000**	**17,000**	**2009 pandemic** • First detected in North America, the 2009 H1N1 pandemic quickly spread to all continents. In the United States, persons at high risk for severe complications included pregnant women and those with neuromuscular disease, lung disease, morbid obesity, and other chronic conditions. • An estimated 43–89 million people in the United States became ill with H1N1 from April 2009 through April 2010, and approximately 12,000 people died.[§] A total of 87% of deaths were among persons aged ≤65 yrs, with a mean age of 43 yrs.[¶] During typical influenza seasons, 80%–90% of deaths are among persons aged ≥65 yrs, and the mean age of influenza-related deaths is approximately 76 yrs.**
		0–18	50,000	1,000	
		18–64	135,000	6,000	
		≥65	155,000	10,000	
Moderate to high severity (moderate to severe pandemic) PSAF quadrant: B	• Clinical severity similar to the range seen during annual influenza seasons. Transmissibility greater than during influenza seasons. • Estimated overall attack and case-fatality rates: 22% and 0.05%, respectively. Rates of severe outcomes are greater than during influenza seasons, especially among younger persons.	**All ages**	**550,000**	**35,000**	**1968 pandemic** • First detected in Hong Kong in July 1968, a new influenza virus (H3N2) spread worldwide. • The first cases in the United States were detected in September 1968. The 1968 influenza pandemic resulted in approximately 30,000 deaths in the United States, with approximately half among those aged ≥65 yrs.††,§§
		0–18	80,000	2,500	
		18–64	220,000	12,000	
		≥65	250,000	20,000	
High severity (severe pandemic) PSAF quadrant: B	• Clinical severity similar to the range seen during annual influenza seasons. Transmissibility greater than during influenza seasons. • Estimated overall attack and case-fatality rates: 28% and 0.1%, respectively. Rates of severe outcomes are greater than during influenza seasons.	**All ages**	**1,100,000**	**86,000**	**1957 pandemic** • A new influenza virus, H2N2 (the Asian strain), emerged in China in February 1957 and spread to approximately 20 countries, including the United States, by June 1957. • An estimated 25% of the U.S. population became ill with the new pandemic virus strain. U.S. infection rates were highest among school-aged children and adults aged ≤40 yrs, with most (64%) of the approximately 70,000 deaths occurring among older adults.††,§§,¶¶
		0–18	150,000	6,000	
		18–64	450,000	30,000	
		≥65	500,000	50,000	
Very high severity (very severe to extreme pandemic) PSAF quadrant: D	• Both clinical severity and transmissibility are greater than during annual influenza seasons. • Estimated overall attack and case-fatality rates: 30% and 1.5%, respectively. Rates of severe outcomes are greater than during influenza seasons, especially among young adults.	**All ages**	**7,500,000**	**1,400,000**	**1918 pandemic** • The 1918 pandemic resulted in death for 2%–3% of those infected, a case-fatality rate that was much greater than the rate during an average influenza season. The pandemic virus was easily transmitted. • Approximately one fourth of the U.S. population became ill, and approximately 500,000 died; 99% of deaths occurred in persons aged ≤65 yrs.††,***
		0–18	1,000,000	100,000	
		18–64	3,000,000	500,000	
		≥65	3,400,000	800,000	

Abbreviation: PSAF = Pandemic Severity Assessment Framework.
*Based on PSAF (**Source:** Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91). Age-specific point estimates of hospitalizations and deaths are based on U.S. Census 2010 population data.
†Point estimates for hospitalizations and deaths, by age group, are based on the estimated overall attack and case-fatality rates provided in the second column (clinical severity and transmissibility). Age-specific point estimates of hospitalizations and deaths are based on U.S. Census 2010 population data.
§**Source:** Shrestha SS, Swerdlow DL, Borse RH, et al. Estimating the burden of 2009 pandemic influenza A (H1N1) in the United States (April 2009–April 2010). Clin Infect Dis 2011;52(Suppl 1):S75–S82.
¶**Source:** Fowlkes AL, Arguin P, Biggerstaff MS, et al. Epidemiology of 2009 pandemic influenza A (H1N1) deaths in the United States, April–July 2009. Clin Infect Dis 2011;52(Suppl 1):S60–S68.
**Source: Viboud C, Miller M, Olson DR, Osterholm M, Simonsen L. Preliminary estimates of mortality and years of life lost associated with the 2009 A/H1N1 pandemic in the U.S. and comparison with past influenza seasons. PLoS Currents 2010;2:RRN1153.
††**Source:** Simonsen L, Clarke MJ, Schonberger LB, Arden NH, Cox NJ, Fukuda K. Pandemic versus epidemic influenza mortality: a pattern of changing age distribution. J Infect Dis 1998;178:53–60.
§§**Source:** Cox NJ, Subbarao K. Global epidemiology of influenza: past and present. Annu Rev Med 2000;51:407–21.
¶¶**Source:** Henderson DA, Courtney B, Inglesby TV, Toner E, Nuzzo JB. Public health and medical responses to the 1957–58 influenza pandemic. Biosecur Bioterror 2009;7:265–73.
***Source: Collins SD. Age and sex incidence of influenza and pneumonia morbidity and mortality in the epidemic of 1928–29 with comparative data for the epidemic of 1918–19. Public Health Rep 1931;46:1909–37.

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TABLE 10. Recommended nonpharmaceutical interventions for influenza pandemics, by setting and pandemic severity*

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Setting	Pandemic severity: Low to moderate severity (mild to moderate pandemic)	High severity (severe pandemic)	Very high severity (very severe to extreme pandemic†)
All	CDC recommends voluntary home isolation of ill persons, respiratory etiquette, hand hygiene, and routine cleaning of frequently touched surfaces and objects.§	CDC recommends voluntary home isolation of ill persons, respiratory etiquette, hand hygiene, and routine cleaning of frequently touched surfaces and objects.	CDC recommends voluntary home isolation of ill persons, respiratory etiquette, hand hygiene, and routine cleaning of frequently touched surfaces and objects.
Residences	CDC generally does not recommend voluntary home quarantine of exposed household members.	CDC might recommend voluntary home quarantine of exposed household members in areas where novel influenza virus circulates.	CDC might recommend voluntary home quarantine of exposed household members in areas where novel influenza virus circulates.
	CDC generally does not recommend use of face masks by ill persons.	CDC might recommend use of face masks by ill persons when crowded community settings cannot be avoided.	CDC might recommend use of face masks by ill persons when crowded community settings cannot be avoided.
Child care facilities, schools for grades K–12, and colleges and universities	CDC might recommend selective school dismissals in facilities serving children at high risk for severe influenza complications.	CDC might recommend temporary preemptive, coordinated dismissals of child care facilities and schools.¶	CDC might recommend temporary preemptive, coordinated dismissals of child care facilities and schools.
		If schools remain open, CDC might recommend social distancing measures.**	If schools remain open, CDC might recommend social distancing measures.
Workplaces	CDC generally does not recommend social distancing measures.	CDC might recommend social distancing measures.††	CDC might recommend social distancing measures.
Mass gatherings§§	CDC generally does not recommend modifications, postponements, or cancellations.	CDC might recommend modifications, postponements, or cancellations.	CDC might recommend modifications, postponements, or cancellations.

Abbreviation: NPI = nonpharmaceutical intervention.
*Personal, community, and environmental NPIs should be 1) initiated early in a pandemic before local epidemics begin to grow exponentially, 2) targeted toward the nexus of transmission (in affected areas where the novel virus circulates), and 3) layered together to reduce community transmission to the greatest extent possible.
†During a very severe or extreme pandemic (similar to the 1918 pandemic), CDC is likely to take an aggressive stance and recommend certain additional NPIs.
§Recommended NPIs are the same for seasonal influenza.
¶Preemptive, coordinated dismissals might be implemented early during a pandemic to decrease the spread of influenza before many students and staff members become ill. Selective dismissals might be implemented by schools that serve students at high risk for complications from infection with influenza. Reactive dismissals might be implemented when many students and staff members are ill and not attending school or when many students and staff members are arriving at school ill and being sent home. Selective and reactive dismissals do not help slow disease transmission in the community.
**Social distancing measures that reduce face-to-face contact in schools might include dividing classes into smaller groups of students who are spaced further apart from each other within the classroom.
††Social distancing measures that reduce face-to-face contact in workplaces might include offering telework and remote meeting options. Flexible sick leave policies should be implemented to encourage workers to stay home if needed.
§§In all scenarios, mass gathering attendance during local outbreaks should be discouraged for persons at high risk for severe influenza-related complications.

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FIGURE 6. U.S. Department of Health and Human Services pandemic planning scenarios based on the Pandemic Severity Assessment Framework

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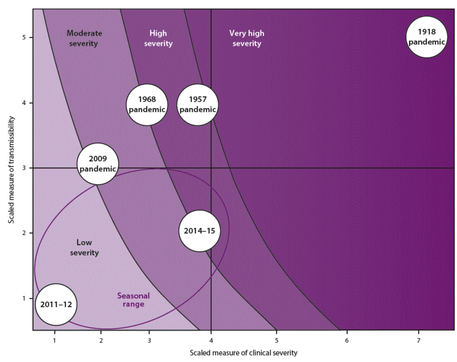

Source: Adapted from: Reed C, Biggerstaff M, Finelli L, et al. Novel framework for assessing epidemiologic effects of influenza epidemics and pandemics. Emerg Infect Dis 2013;19:85–91.

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Suggested citation for this article: Qualls N, Levitt A, Kanade N, et al. Community Mitigation Guidelines to Prevent Pandemic Influenza — United States, 2017. MMWR Recomm Rep 2017;66(No. RR-1):1–34. DOI: http://dx.doi.org/10.15585/mmwr.rr6601a1 .

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Exhibit C

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Il Bacco Restaurant Corp., Sid Boys Corp. d/b/a Kellogg's Diner, 143 Cafe Inc. d/b/a Toscana, 22 Cafe Inc. d/b/a Osteria Del Blanca,

Plaintiff,

DECLARATION OF DR. JAYANTA BHATTACHARYA

Against

Civil No.:

ANDREW M. CUOMO, in his Official Capacity as Governor of the State of New York, ATTORNEY GENERAL OF THE STATE OF NEW YORK, and THE STATE OF NEW YORK,

Defendants.

Dr. Jayanta Bhattacharya, on the date noted below and pursuant to § 1746 of title 28 of the United States Code, declares the following to be true and correct under penalty of perjury under the laws of the United States of America:

I, Dr. Jayanta Bhattacharya, declare as follows:

1. I am a Professor of Medicine at Stanford University and have been on the Stanford University faculty since 2001. I have firsthand, personal knowledge of the facts set forth below and if called as a witness could competently testify thereto.

2. As described more fully below, based on my education, training, experience and ongoing review of the academic literature in the context of COVID-19, my professional medical and scientific opinion is that the blanket prohibition on indoor dining in New York City does not comport with, and in fact is inconsistent with, good public health practice applicable to COVID-19.

3. It is also my professional medical and scientific opinion that restaurants in New York City can safely permit indoor dining to occur on their premises by following the guidelines set forth by the State of New York in its "Reopening New York-New York City Indoor Food Services Guidelines for Employees and Employers."

Professional Background

4. I have an MD and a Ph.D. in economics, both earned from Stanford University. I am the director of the Stanford Center for Demography and Economics of Health and Aging. At Stanford, I teach courses on health economics in the Economics Department and on advanced statistical methods in the School of Medicine.

5. My primary research area is health economics, including a focus on epidemiology and infectious disease epidemiology. Between 1996 and 2020, I have published 136 articles in peer-reviewed journals, including top-ranked journals in economics, statistics, public health, epidemiology, medicine, and health policy literature.

6. I have published numerous papers on the economics and medicine of infectious disease, including on the economics and epidemiology of HIV, H1N1 flu, H5N1 flu, seasonal influenza, antimicrobial resistance and antibiotic use, and COVID-19.

7. I have written a popular textbook, *Health Economics*, used to teach the subject in universities around the world. The textbook includes a chapter on economic epidemiology that surveys the literature on disease modeling, including compartment models such as the Susceptible-Infected-Recovered (SIR) models, commonly in use to forecast the COVID-19 epidemic.

8. I have been actively researching the COVID-19 epidemic using my expertise in infectious disease epidemiology and health economics. To date, I have published three papers in peer-reviewed journals related to the epidemic. In addition, I have written two articles that are currently under consideration at peer-reviewed journals, and I have published multiple editorials, including three on economic[1] and epidemiological[2] issues related to the epidemic and an editorial[3] on optimal public health management of the epidemic.

9. In the course of my recent research, I have become particularly familiar with the dynamics of the COVID-19 epidemic in Los Angeles County. My published papers on COVID-19 include the first published serological study measuring the prevalence of the COVID-19 epidemic. This study, conducted in Los Angeles County ("LA County"), uses evidence from a specific antibody response to SARS-CoV-2 (the virus that causes COVID-19) infection in an adult community-dwelling sample picked to be representative of the county. This piece was published in the *Journal of the American Medical Association*, one of the leading peer-reviewed journals in medicine. This paper finds that by April 10-11, 2020, 4.3% of LA County adults show specific

[1] (Jay Bhattacharya & Mikko Packalen, *Lives vs Lives: The Global Cost of Lockdown* (May 13, 2020) SPECTATOR USA, https://bit.ly/3j4mJrx.)
[2] (Eran Bendavid & Jay Bhattacharya, *Is the Coronavirus as Deadly as They Say?* (March 24, 2020) WSJ OPINION, https://on.wsj.com/3lgEWV1.)
[3] (Jay Bhattacharya & Sanjiv Agarwal, *Lift lockdowns, protect the vulnerable, treat Covid like a health issue and not a disaster* (July 24, 2020) THE PRINT, https://bit.ly/2QeNzAO.)

antibody evidence of prior or current COVID-19 infection. This prevalence rate represents a multiple of 43.5 times the number of cases confirmed by the county public health authority by that date. One important implication of this paper is that the infection fatality rate from COVID-19 in LA County up to the date of the survey (that is, the probability of dying from a SARS-CoV-2 infection) is at least an order of magnitude lower than the case fatality rate. The case fatality rate includes only patients who were infected with SARS-CoV-2 and identified as a case in the denominator of the calculation. Cases most typically include patients who have severe symptoms and thus come to the attention of medical authorities. Our study shows that cases represent only a small fraction of the set of people who have been infected with SARS-CoV-2. I served as the senior author for this article.

10. I have also published a second peer-reviewed paper in the *Journal of Public Health* on racial disparities in knowledge and attitudes regarding the danger posed by COVID-19 infection and the efficacy of personal behaviors like hand washing and social distancing in protecting against infection. I reviewed the literature cited in the paper regarding best practices for personal protection to prevent exposure to SARS-CoV-2.

11. I am a co-author of a paper titled "Visualizing the Invisible: The Effect of Asymptomatic Transmission on the Outbreak Dynamics of COVID-19." Recently published in *Computer Methods in Applied Mechanics and Engineering*.[4] This paper presents the first forecasting model that accounts for data provided by seroprevalence studies such as the LA County study. In particular, the model accounts for the vast population of previously infected people identified by the seroprevalence studies and challenges the notion that contact tracing can be a viable strategy to control the further spread of COVID-19 infection.

[4] Mathias Peirlinck, Kevin Linka, Francisco Sahli Costabal, Jay Bhattacharya, Eran Bendavid, John Ioannidis, Ellen Kuhl (2020), "Visualizing the Invisible: The Effect of Asymptotic Transmission on the Outbreak Dynamics of COVID-19" *Computer Methods in Applied Mechanics and Engineering*. 372: 1 Dec. 2020, 113410. https://doi.org/10.1016/j.cma.2020.113410.

12. I currently have two unpublished papers on COVID-19 presently undergoing peer review reporting on seroprevalence studies. I am the senior author of the Santa Clara County ("SCC") seroprevalence study. It is the first seroprevalence study where the study team made a scientific paper available (undergoing peer review), and it is still, to my knowledge, the largest community seroprevalence survey in the US. The results from SCC were similar to the results from the LA County seroprevalence study. On April 3rd & 4th, 2020, the seroprevalence of SARS-CoV-2 antibodies in the SCC sample, reweighted to match the zip code of residence, sex, and race distribution of SCC, was 2.8%. The SCC study has been enormously influential and has served as a template for the many seroprevalence studies that have followed it. The preprint article reporting on the SCC study, though not peer-reviewed, has generated 301 citations (according to Google Scholar accessed on November 27, 2020) to date.

13. I am also the senior author of a study (still undergoing peer review) measuring the seroprevalence of SARS-CoV-2 infection among employees of Major League Baseball on April 14th & 15th, 2020. This is the first seroprevalence study of national scope measuring the extent of COVID-19. The main finding from that study is that, as of the date of data collection, the prevalence of current or prior COVID-19 infection in the MLB employee population was 0.7%. In addition to my published work, over the past seven months, I have been invited to serve as a peer reviewer for many scientific journals to review COVID-19 related submissions by other scientists. These journals include the *British Medical Journal*, *Health Affairs*, the *Journal of Infectious Disease*, and the *Annals of Internal Medicine*. For these journals, I have provided scientific advice regarding the publication of articles on topics related to the COVID-19 epidemic.

14. In May 2020, I testified at a virtual roundtable organized by United States Senator Pat Toomey on the subject of the potential reopening of youth baseball leagues while protecting the safety of participants. At this roundtable, I reviewed the evidence regarding the relatively low

mortality and morbidity risk that SARS-CoV-2 infection poses to children and adolescents, and I discussed social distancing and other protocols to make youth baseball safer for coaches, umpires, and other adult participants.

15. In July 2020, I was invited to testify at a House Oversight Briefing to the Economic and Consumer Policy Subcommittee on SARS-CoV-2 vaccine development. My testimony focused on the randomized trials and other studies currently underway to produce a safe and effective vaccine to SARS-CoV-2 infection, and in particular on the confidence that the public can have on the US Food and Drug Administration's (FDA) evaluation of the scientific evidence regarding new vaccines.

16. In September 2020, I participated in an invited live roundtable discussion led by Florida Governor Ron DeSantis on the evidence regarding the safety of reopening Florida and the health harms from continued lockdown.[5] My testimony presented the scientific evidence on the infection fatality rate from COVID-19 infection by age, the collateral damage from lockdowns on physical and psychological health, and on the safety of opening schools for in-person instruction. In October 2020, Harvard Professor Dr. Martin Kulldorff invited me and Oxford Professor Dr. Sunetra Gupta to travel to Great Barrington, Massachusetts to record a video outlining an alternative to the current COVID-19 strategies being implemented in jurisdictions across the United States. While meeting, we spontaneously decided to write a short Declaration summarizing our thinking. The Declaration was written from a global public health and humanitarian perspective, with special concerns about how the current COVID-19 strategies are forcing our children, the working class and the poor to carry the heaviest burden.

[5] Orlando Sentinel Staff (2020) Gov. DeSantis Leads Coronavirus Discussion https://www.orlandosentinel.com/news/breaking-news/os-ne-desantis-coronavirus-discussion-thursday-20200924-uhteut5vmfclno74sijewv25zu-story.html. Accessed 10/7/2020

17. The Declaration offers an alternative approach called Focused Protection. According to Focused Protection, the most compassionate approach to the COVID-19 pandemic is one that allows those who are at minimal risk of death to live their lives normally to avoid lockdown harms, while better protecting those who are at highest risk from COVID-19 infection.

18. After finishing the Declaration, Professors Kulldorff, Gupta, and I contacted esteemed colleagues working as medical and public health scientists or medical practitioners to invite them to sign the Declaration. The Declaration was then published with approximately 30 co-signers in early October. Since that time, the Declaration has been co-signed by more than 12,000 medical and public health scientists, and 35,000 medical practitioners. The Great Barrington Declaration is available at https://gbdeclaration.org/.

The State of New York Executive Order to shutdown Indoor Dining is Inconsistent with the Statewide Contact Tracing Data

19. I understand that the Governor of New York currently claims that the epidemiological science of infectious disease control in the context of COVID-19, and specifically in the context of COVID-19 data in New York State, requires that a total city-wide prohibition on in-person indoor dining at any restaurant in New York City be implemented on December 14, 2020 for an indefinite period of time and further wiping out the restaurant industry in New York City.

20. In the paragraphs that follow, drawn both from my own work and from the scientific literature on COVID-19, I discuss New York City guidelines on indoor dining; (2) the Governor's prohibition on indoor dining in New York City; (3) the mortality risk from COVID-19 infection for patients of different ages; and (4) the public health community's approval of the principle that individuals and groups may appropriately take actions that raise the risk of COVID-

19 infection if the value provided by those actions to participants is sufficiently large to outweigh the infection-related harms relative to other activities that might provide similar benefits.

21. To prepare this declaration, I have reviewed the Reopening Guidance issued by the State of New York for New York City Indoor Dining issued on or about September 11, 2020.

https://www.governor.ny.gov/sites/governor.ny.gov/files/atoms/files/NYC_Indoor_Food_Services_Detailed_Guidance.pdf

22. This aforementioned document provides guidance for restaurants seeking to safely conduct operations. Consistent with this guidance, indoor dining may occur with relative safety at restaurants in New York City if precautionary measures including, but not limited to, social distancing and mask wearing by servers and by patrons (when not eating) are observed. The guidance limited indoor capacity to no more than 25% of maximum capacity, only permit employees or patrons if they have their temperature taken before or immediately entering the establishment and have a temperature no greater than 100 degrees F, and one person from each party must provide the full name, address and phone number for use in contract tracing efforts. Seating and service was also prohibited at bars and other reasonable accommodations such as spacing tables appropriately, all employees must wear acceptable face covering at all times, frequent sanitizing of surfaces, and other actions that are well within the capability of NYC restaurants. Accordingly, the guidelines put in place have worked well because restaurants and bars in New York City only account for 1.4% of the COVID spread.

https://ny.eater.com/2020/12/11/22169841/restaurants-and-bars-coronavirus-spread-data-new-york

23. According to the data, private gatherings at home account for 74% of the covid spread.

24. It is my professional opinion that restaurants in New York City can safely permit indoor dining to occur on their premises by continuing to follow the guidelines set forth by the State of New York.

25. The State of New York has ordered that restaurants and bars may only offer food and beverage via take-out, outdoor dining if available or delivery, and that "any service of food, beverages and/or alcohol that involves a customer sitting or remaining onsite" "indoors" "to consume food or beverages is prohibited." Though I have read many of the contact tracing studies in the scientific literature that document the most common sources of spread of COVID infection, I am aware of no evidence to suggest that indoor dining is more likely to result in the spread the COVID-19 virus than the permitted venues such as casinos, bowling alleys, museums, Target stores, Walmart – including private gatherings – that remain permissible and, in fact, will be more likely in the event that this order remains in effect.

26. On top of these considerations, I note that the City of New York guidelines and order prohibiting indoor dining are substantively stricter than is required by other restaurants outside of New York City. Restaurants outside of New York City do not have to take temperatures or contact trace and can fill restaurants up to 50% of maximum capacity.

27. The numbers show that the decision to close NYC restaurants does not add up to the numbers. New York City has the second lowest infection rate in the State over the last seven days, an average at 4.0%. The infection rates of the surrounding counties are significantly higher than New York City, yet the restaurants in those counties can operate at 50% of maximum capacity while New York City restaurants have been ordered to be shut down.

https://forward.ny.gov/percentage-positive-results-region-dashboard

28. Nassau County has an infection rate of 5.2%, Westchester County has an infection rate of 5.9% and Suffolk County has an infection rate of 6.0%. All three counties border New York City and have significant higher infection rates than New York City (4.0%). https://forward.ny.gov/percentage-positive-results-county-dashboard

29. By prohibiting indoor on-premises dining and doing so throughout the City of New York, the State of New York is imposing stricter requirements than necessary. However, it is doing so without a scientific justification for imposing such stricter requirements on these activities. The data available does not contain any epidemiological or other model that shows that, for example, prohibiting indoor dining in New York City has any relationship whatsoever to avoiding circumstances that "challeng[e] our healthcare delivery system's ability to surge with space, supplies and staff," does not compare hospitalization forecasts against hospital capacity in light of prohibitions on indoor dining, does not account for the possibility of transfers of patients across to other counties, nor account for the possibility of building and staffing field hospitals in overstretched areas. Absent modeling that makes explicit assumptions about these details, the claimed benefits of restricting indoor dining as the State of New York has purported to do lacks adequate scientific justification.

30. In addition to the lack of scientific evidence establishing the public health benefits of prohibiting indoor dining on a county-wide basis as effectuated by the State of New York's recent order, the State of New York Department of Health has provided no indication that it has estimated or otherwise taken into account any of the economic, social and public health costs of restricting indoor dining. Basic standards of public health policy design require a comparison of both costs and benefits of a policy to justify it from a scientific and ethical point of view. There is no discussion or provision of data whatsoever regarding the very substantial costs that arise from

prohibitions such as that imposed by the State of New York and Governor Cuomo. A scientifically justified policy must explicitly account for these costs – including an explicitly articulated economic analysis – in setting, imposing and removing criteria for business restrictions such as the blanket prohibition on indoor dining. The State has provided no such analysis in its publicly available materials regarding its prohibition on indoor dining in New York City. I am aware of no such analysis that exists.

Mortality Risk from COVID-19 Infection vs. Costs of Blanket and Untargeted Prohibition on Outdoor Dining

31. The mortality rates being used as a justification for the ban on indoor dining similarly lack a rational medical and scientific basis. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase - polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards.

32. According to a meta-analysis[6] by Dr. John Ioannidis of every seroprevalence study conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities around the world), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of

[6] (John P.A. Ioannidis, *The Infection Fatality Rate of COVID-19 Inferred from Seroprevalence Data,* Bulletin of the World Health Organization BLT.20.265892.)

99.95%. A newly released meta-analysis[7] by analysts independent of Dr. Ioannidis' group, reaches qualitatively similar conclusions.

33. A CDC report[8] found that there were between six and 24 times more SARS-CoV-2 infections than cases reported between March and May 2020. This study is based on serological analysis of blood samples incidentally collected by commercial laboratories in 10 cities nationwide. Though the CDC does not provide the infection fatality rate estimate implied by their seroprevalence estimate in their report, the multiplier to cases they report is in line with the seroprevalence studies reviewed by Dr. Ioannidis above.

34. In September 2020, the CDC updated its current best estimate of the infection fatality ratio—the ratio of deaths to the total number of people infected—for various age groups.[9] The CDC estimates that the infection fatality rate for people ages 0-19 years is .00003, meaning infected children have a 99.997% infection survivability rate.[10] The CDC's best estimate of the infection fatality rate for people ages 20-49 years is .0002, meaning that young adults have a 99.98% survivability rate.[11] The CDC's best estimate of the infection fatality rate for people age 50-69 years is .005, meaning this age group has a 99.5% survivability rate.[12] The CDC's best estimate of the infection fatality rate for people ages 70+ years is .054, meaning seniors have a 94.6% survivability rate.[13]

35. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a

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[7] (Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications* (Aug. 14, 2020) MEDRXIV, https://bit.ly/3gpIoIV.)
[8] (Fiona P. Havers, et al., *Seroprevalence of Antibodies to SARS-CoV-2 in 10 Sites in the United States, March 23-May 12, 2020* (Jul. 21, 2020) JAMA INTERN MED., https://bit.ly/3goZUgy.)
[9] COVID-19 Pandemic Planning Scenarios, Centers for Disease Control and Prevention, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.
[10] *Id.*
[11] *Id.*
[12] *Id.*
[13] *Id.*

vanishingly small risk. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies. Three such studies (of which I am currently aware) provide age-specific infection fatality rate estimates. The CDC's current best estimates are that the symptomatic fatality rate from COVID-19 among patients less than 50 years old is 0.05%, or 5 in 10,000; 0.2% for patients between ages 50 and 64; and 1.3% for patients 65 and above. The infection fatality rates are lower than these numbers since only a fraction of patients are symptomatic.

36. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)[14] provides a detailed age break down of the infection survival rate in a preprint companion paper[15]: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65.

37. Indoor dining typically includes people of all ages in attendance. However, the scientific evidence discussed above shows that for the non-elderly diners present, the mortality risk conditional on contracting the disease is very low. The infection survival rate is more than 99.8% for this population according to the estimates cited above that come from the US. Even this number overestimates the risk of outdoor dining, since the probability of contracting the disease during the service is much less than one, though difficult to estimate given available public health information.

38. These risks are still lower if the precautions required to be followed by restaurants (mask wearing, social distancing, spacing and hand washing, among others) are followed.

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[14] (Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study* (June 11, 2020) THE LANCET, https://bit.ly/3l87S13.).

[15] (Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland* (June 15, 2020) OSF PREPRINTS, https://osf.io/wdbpe/.)

39. Against this data regarding the negligible risks of COVID-19 transmission in indoor dining should be considered the substantial evidence that social eating provides significant and tangible psychological and physiological benefits for diners that are lost through the imposition of such scientifically and epidemiologically unjustified blanket and untargeted bans. Those who eat socially more often feel happier and are more satisfied with life, are more trusting of others, are more engaged with their local communities, and have more friends they can depend on for support; path analysis suggests that the causal connection runs from eating together to bondedness rather than the other way around.[16] Dining together reduces people's perceptions of inequality and contributes to a view of those of different races, genders and socioeconomic backgrounds as more equal than in other social scenarios.[17] And a comprehensive survey of 17,612 men and 19,581 women over the age of 65 found that eating alone has been linked to a higher incidence of depression among adults, particularly those who live alone.[18] Eliminating the possibility of indoor dining, no matter the precautions taken, reduces or eliminates these important benefits.

40. Moreover – and significantly – prohibiting indoor dining in New York City as the State of New York has purported to do raises the likelihood of uncontrolled private indoor gatherings, which carry with them a substantially higher risk of transmission of the virus if precautions are not taken.

Urban Population Density and Asymptomatic Disease Spread

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[16] (Dunbar, *Breaking Bread: the Functions of Social Eating*, *Adaptive Human Behavior and Physiology* (*available at* https://link.springer.com/article/10.1007/s40750-017-0061-4)).

[17] (Julier, *Eating Together: Food, Friendship and Inequality*, The University of Illinois Press (2014)).

[18] Tani, et al, *Eating alone and depression in older men and women by cohabitation status: the JAGES longitudinal survey*, *Age Ageing* 44(6) 1019-1026 (2015) (*available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4621239/).

41. New York City is obviously a heavily urbanized city with a high population density. This fact alone, however, does not justify restrictions on indoor dining when restaurants comply with the city's safe reopening guidelines (listed above). First, the mechanism that links urban density and high disease spread runs primarily through New York City's subway system, not through its restaurants. In March 2020, the boroughs that had the greatest drops in subway ridership also experienced the least disease spread.[19]

42. Second, as long as affected restaurants comply with New York City reopening guidelines, merely having dense urban spaces outside of the affected restaurants does not create greater risk of Covid-19 transmission inside the spaces of the affected restaurants. The key reason is that the reopening guidelines require that New York City's restaurants check potential patrons for symptoms consistent with COVID-19 disease, permitting only people without symptoms to enter the premises and dine indoors. Numerous lines of evidence establish that SARS-CoV-2 infected patients with no symptoms are much less efficient at spreading the disease than people with symptoms. A meta-analysis of 54 studies from around the world found that within households – where none of the safeguards that restaurants are required to apply are typically applied – symptomatic patients passed on the disease to household members in 18% of instances, while asymptomatic patients passed on the disease to household members in 0.7% of instances.[20] A large study of 10 million residents of Wuhan, China, all tested for the presence of the virus, found a total of 300 total cases, all asymptomatic. A comprehensive contact tracing effort identified 1,174 close contacts of these patients, none of whom tested positive for the virus.[21] This

[19] (Jeffrey E. Harris. The Subways Seeded the Massive Coronavirus Epidemic in New York City. National Bureau of Economic Research Working Paper #27021. April 2020. DOI 10.3386/w27021)

[20] (Madewell ZJ, Yang Y, Longini IM, Halloran ME, Dean NE. Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis. *JAMA Netw Open*. 2020;3(12):e2031756. doi:10.1001/jamanetworkopen.2020.31756)

is consistent with a vanishingly low level of asymptomatic spread of the disease. While theoretical modeling work from earlier in the epidemic (including some of my own published research[22]) predicts some level of asymptomatic disease spread, the empirical evidence at this point later in the epidemic strongly shows very little evidence that this is an important empirical reality. So as long as restaurants follow New York City's guidelines to exclude potential symptomatic diners, in-patient dining can occur safely despite the city's high population density.

Public Health Principles Accept Trade-Offs

43. The final question I address in my declaration is a principle promoted by public health experts and the public health community that implies that certain action may be justified despite some public health risk if the action is sufficiently important to warrant it.

44. For example, the Black Lives Matter (BLM) protests started nationwide shortly after the killing of George Floyd in Minnesota on May 25th, 2020. One press account[23] in early June suggests that more than 26 million Americans nationwide (primarily in big cities, but also elsewhere) have participated in at least one protest since the first protests started on May 26th, 2020.

45. Protest organizers have manifestly not followed WHO or CDC guidelines regarding the conduct of large-scale events during the COVID-19 epidemic. Prominent public

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[21] (Cao, S., Gan, Y., Wang, C. et al. Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. *Nat Commun* 11, 5917 (2020). https://doi.org/10.1038/s41467-020-19802-w)

[22] (Peirlinck et al., *op cit*.)

[23] (Matthew Wright, *Black Lives Matter Protests May be the Largest in U.S. History as More Than 26 Million Americans Have Been at the More Than 4, 700 Demonstrations Around the Country* (July 8, 2020) DAILY MAIL, http://dailym.ai/2Qif6kU.)

officials have participated in BLM protests that violate guidelines regarding the use of masks[24] and maintained social distancing during large events.

46. The reaction[25] of many prominent voices[26] within the public health community to the BLM protests has emphasized the importance of the right of Americans concerned about racial injustice to protest despite COVID-19. Nearly 1,300 public health experts signed a public letter[27] supporting the right of BLM protestors to gather publicly because of their (the protestors' and the public health experts') deeply held opposition to systemic racism. The letter explicitly acknowledged that social distancing and public masking would minimize the spread of COVID-19 and urged "to the extent possible" that these practices be followed by demonstrators while recognizing that protestors would not always be able to follow these guidelines. The signatories, in effect, weighed the costs of the protests (some risk of COVID-19 disease spread and mortality) against the benefits (support for a cause they deem worthy) and concluded in favor of the BLM demonstrations.

47. The principle the public letter supports is entirely reasonable: public health recommendations regarding behavior by private actors (such as the decision to protest) should weigh the benefits of that behavior against the public health costs. Though the signatories of the letter express their own support for the cause underlying the BLM protests, this principle cannot be contingent on their support of those particular activities alone. If this contingency were necessary, the charge by other public health experts[28] that the signatories are hypocritical in their

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[24] (Jaclyn Cosgrove, et al., *Mayor Garcetti takes a knee amid chants of 'Defund police!' at downtown L.A. protest* (Jun. 2, 2020) LOS ANGELES TIMES, https://lat.ms/34oEbDh.)
[25] (Rachel Weiner, *Political and Health Leaders' Embrace of Floyd Protests Fuels Debate Over Coronavirus Restrictions* (Jun. 11, 2020) THE WASHINGTON POST, https://wapo.st/3gmZKGD.)
[26] Dan Diamond, *Suddenly, Public Health Officials Say Social Justice Matters More Than Social Distance* (Jun. 4, 2020) POLITICO, https://politi.co/3gfOxHK.)
[27] (*Open Letter Advocating for an Anti-Racist Public Health Response to Demonstrations Against Systemic Injustice Occurring During the COVID-19 Pandemic*, GOOGLE DRIVE, https://bit.ly/3hmO6N4 [accessed July 9, 2020].)

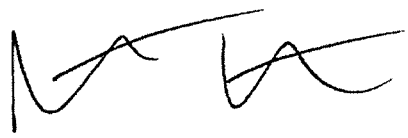
support of masks, social distancing, and social isolation to reduce COVID-19 spread would be correct.

48. If the benefits of the undertaking are important enough relative to the public health risks and care is taken to minimize those risks by adhering to the extent possible to safe practice guidelines promulgated by public health authorities, then the activity should receive approval by public health experts.

In summary, based on my education, experience and ongoing review of the academic literature in the context of COVID-19, my professional medical and scientific opinion is that the blanket New York State prohibition on indoor dining in New York City does not comport with, and in fact is inconsistent with, the epidemiology and infectious disease epidemiological knowledge applicable to COVID-19. Reversing – rather than continuing – this inappropriate untargeted ban is entirely consistent with good public health practice. It is also my professional medical and scientific opinion that restaurants in New York City can safely permit indoor dining to occur on their premises by following the guidelines set forth by the State of New York Reopening Plan for New York City Indoor Dining.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed this 14th day of December, 2020 at Los Altos, California.



Dr. Jayanta Bhattcharya

[28] (Joseph S. Ladapo, *The Coronavirus Credibility Gap* (July 1, 2020) WSJ OPINION, https://on.wsj.com/3hoIKRq.)

Exhibit D

The NEW ENGLAND JOURNAL of MEDICINE

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ORIGINAL ARTICLE

SARS-CoV-2 Transmission among Marine Recruits during Quarantine

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December 17, 2020
N Engl J Med 2020; 383:2407-2416
DOI: 10.1056/NEJMoa2029717

Article Figures/Media

Metrics

14 References

13 Citing Articles
2 Comments
Related Articles

Abstract

BACKGROUND

The efficacy of public health measures to control the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has not been well studied in young adults.

METHODS

We investigated SARS-CoV-2 infections among U.S. Marine Corps recruits who underwent a 2-week quarantine at home followed by a second supervised 2-week quarantine at a closed college campus that involved mask wearing, social distancing, and daily temperature and symptom monitoring. Study volunteers were tested for SARS-CoV-2 by means of quantitative polymerase-chain-reaction (qPCR) assay of nares swab specimens obtained between the time of arrival and the second day of supervised quarantine and on days 7 and 14. Recruits who did not volunteer for the study underwent qPCR testing only on day 14, at the end of the quarantine period. We performed phylogenetic analysis of viral genomes obtained from infected study volunteers to identify clusters and to assess the epidemiologic features of infections.

RESULTS

A total of 1848 recruits volunteered to participate in the study; within 2 days after arrival on campus, 16 (0.9%) tested positive for SARS-CoV-2, 15 of whom were asymptomatic. An additional 35 participants (1.9%) tested positive on day 7 or on day 14. Five of the 51 participants (9.8%) who tested positive at any time had symptoms in the week before a positive qPCR test. Of the recruits who declined to participate in the study, 26 (1.7%) of the 1554 recruits with available qPCR results tested positive on day 14. No SARS-CoV-2 infections were identified through clinical qPCR testing performed as a result of daily symptom monitoring. Analysis of 36 SARS-CoV-2 genomes obtained from 32 participants revealed six transmission clusters among 18 participants. Epidemiologic analysis supported multiple local transmission events, including transmission between roommates and among recruits within the same platoon.

CONCLUSIONS

Among Marine Corps recruits, approximately 2% who had previously had negative results for SARS-CoV-

2 at the beginning of supervised quarantine, and less than 2% of recruits with unknown previous status, tested positive by day 14. Most recruits who tested positive were asymptomatic, and no infections were detected through daily symptom monitoring. Transmission clusters occurred within platoons. (Funded by the Defense Health Agency and others.)

Introduction

Prospective studies may be useful to inform strategies to mitigate the transmission of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), particularly in group settings among young adults.[1-4] U.S. Department of Defense installations have implemented recommended public health interventions.[5] However, confined living spaces, close contact among persons during training regimens and other activities, shared dining facilities, and mixing of persons from across the United States place military populations at risk for contracting contagious respiratory infections such as coronavirus disease 2019 (Covid-19).[6-9] The transmission of SARS-CoV-2 and Covid-19 in military settings has not been well studied.

The public health program implemented by the U.S. Marine Corps for all new recruits includes a period of home quarantine followed by a 2-week, strictly supervised quarantine at a closed campus, with the objective of mitigating infection among recruits. To evaluate the effectiveness of these measures, we monitored SARS-CoV-2 infections with serial real-time quantitative polymerase-chain-reaction (qPCR) assays and assessed events of virus transmission by means of phylogenetic analysis of viral genomes obtained from infected participants.

Methods

STUDY DESIGN AND PARTICIPANTS

To reduce the risk of introducing SARS-CoV-2 into basic training at Marine Corps Recruit Depot, Parris Island, in South Carolina, the Marine Corps established a 14-day supervised quarantine period at a college campus used exclusively for this purpose. Potential recruits were instructed to quarantine at home for 2 weeks immediately before they traveled to campus. At the end of the second, supervised quarantine on campus, all recruits were required to have a negative qPCR result before they could enter Parris Island. Recruits were asked to participate in the COVID-19 Health Action Response for Marines (CHARM) study, which included weekly qPCR testing and blood sampling for IgG antibody assessment.

After potential recruits had completed the 14-day home quarantine, they presented to a local Military Entrance Processing Station, where a medical history was taken and a physical examination was performed. If potential recruits were deemed to be physically and mentally fit for enlistment, they were instructed to wear masks at all times and maintain social distancing of at least 6 feet during travel to the quarantine campus. Classes of 350 to 450 recruits arrived on campus nearly weekly. New classes were divided into platoons of 50 to 60 recruits, and roommates were assigned independently of participation in the CHARM study. Overlapping classes were housed in different dormitories and had different dining times and training schedules.

During the supervised quarantine, public health measures were enforced to suppress SARS-CoV-2 transmission (Table S1 in the **Supplementary Appendix**, available with the full text of this article at NEJM.org). All recruits wore double-layered cloth masks at all times indoors and outdoors, except when sleeping or eating; practiced social distancing of at least 6 feet; were not allowed to leave campus; did not have access to personal electronics and other items that might contribute to surface transmission; and routinely washed their hands. They slept in double-occupancy rooms with sinks, ate in shared dining facilities, and used shared bathrooms. All recruits cleaned their rooms daily, sanitized bathrooms after each use with bleach wipes, and ate preplated meals in a dining hall that was cleaned with bleach after each platoon had eaten. Most instruction and exercises were conducted outdoors. All movement of recruits was supervised, and unidirectional flow was implemented, with designated building entry and exit points to minimize contact among persons. All recruits, regardless of participation in the study, underwent daily temperature and symptom screening. Six instructors who were assigned to each platoon worked in 8-hour shifts and enforced the quarantine measures. If recruits reported any signs or symptoms consistent with Covid-19, they reported to sick call, underwent rapid qPCR testing for SARS-CoV-2, and were placed in isolation pending the results of testing.

Instructors were also restricted to campus, were required to wear masks, were provided with preplated meals, and underwent daily temperature checks and symptom screening. Instructors who were assigned to a platoon in which a positive case was diagnosed underwent rapid qPCR testing for SARS-CoV-2, and, if the result was positive, the instructor was removed from duty. Recruits and instructors were prohibited from interacting with campus support staff, such as janitorial and food-service personnel. After each class completed quarantine, a deep bleach cleaning of surfaces was performed in the bathrooms, showers, bedrooms, and hallways in the dormitories, and the dormitory remained unoccupied for at least 72 hours before reoccupancy.

Within 2 days after arrival at the campus, after recruits had received assignments to platoons and roommates, they were offered the opportunity to participate in the longitudinal CHARM study. Recruits

were eligible if they were 18 years of age or older and if they would be available for follow-up. The study was approved by the institutional review board of the Naval Medical Research Center and complied with all applicable federal regulations governing the protection of human subjects. All participants provided written informed consent.

PROCEDURES

At the time of enrollment, participants answered a questionnaire regarding demographic characteristics, risk factors for SARS-CoV-2 infection, symptoms within the previous 14 days, and a brief medical history; blood samples and mid-turbinate nares swab specimens were obtained for qPCR testing to detect SARS-CoV-2. Demographic information included sex, age, ethnic group, race, place of birth, and U.S. state or country of residence; information regarding risk factors included whether participants had used masks, whether they had adhered to self-quarantine before arrival, their recent travel history, their known exposure to someone with Covid-19, whether they had flulike symptoms or other respiratory illness, and whether they had any of 14 specific symptoms characteristic of Covid-19 or any other symptoms associated with an unspecified condition within the previous 14 days.

Study participants were followed up on days 7 and 14, at which time they reported any symptoms that had occurred within the past 7 days. Nares swab specimens for repeat qPCR assays were also obtained. Participants who had positive qPCR results were placed in isolation and were approached for participation in a related but separate study of infected recruits, which involved more frequent testing during isolation. All recruits who did not participate in the current study were tested for SARS-CoV-2 only at the end of the 2-week quarantine, unless clinically indicated (in accordance with the public health procedures of the Marine Corps). Serum specimens obtained at enrollment were tested for SARS-CoV-2–specific IgG antibodies with the use of the methods described below and in the Supplementary Appendix.

Participants who tested positive on the day of enrollment (day 0) or on day 7 or day 14 were separated from their roommates and were placed in isolation. Otherwise, participants and nonparticipants were not treated differently: they followed the same safety protocols, were assigned to rooms and platoons regardless of participation in the study, and received the same formal instruction.

LABORATORY METHODS

The qPCR testing of mid-turbinate nares swab specimens for SARS-CoV-2 was performed within 48 hours after collection by Lab24 (Boca Raton, FL) with the use of the TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific), which is authorized by the Food and Drug Administration. Specimens obtained from nonparticipants were tested by the Naval Medical Research Center (Silver Spring, MD).

Specimens were stored in viral transport medium at 4°C. The presence of IgG antibodies specific to the SARS-CoV-2 receptor-binding (spike) domain in serum specimens was evaluated with the use of an enzyme-linked immunosorbent assay, as previously described,[10] with some modifications. At least two positive controls, eight negative controls (serum specimens obtained before July 2019), and four blanks (no serum) were included in every plate. Serum specimens were first screened at a 1:50 dilution, followed by full dilution series if the specimens were initially found to be positive.

WHOLE-GENOME SEQUENCING AND ASSEMBLY

SARS-CoV-2 sequencing was performed with the use of two sequencing protocols (an Illumina sequencing protocol and an Ion Torrent sequencing protocol) to increase the likelihood of obtaining complete genome sequences. A custom reference-based analysis pipeline (https://github.com/mjsull/COVID_pipe) was used to assemble SARS-CoV-2 genomes with the use of data from Illumina, Ion Torrent, or both.[11]

PHYLOGENETIC ANALYSIS

SARS-CoV-2 genomes obtained from patients worldwide and associated metadata were downloaded from the Global Initiative on Sharing All Influenza Data EpiCoV database[12] on August 11, 2020 (79,840 sequences), and a subset of sequences was selected from this database with the use of the default subsampling scheme of Nextstrain software[13] with the aim of maximizing representation of genomes obtained from patients in the United States. Phylogenetic analyses of the specimens obtained from participants were performed with the v1.0-292-ga9de690 Nextstrain build for SARS-CoV-2 genomes with the use of default parameters. Transmission and outbreak events were identified on the basis of clustering of the SARS-CoV-2 genomes obtained from study participants within the Nextstrain phylogenetic tree, visualized with TreeTime.[14] A comparative analysis of mutation profiles relative to the SARS-CoV-2 Wuhan reference genome was performed with the use of Nextclade software, version 0.3.6 (https://clades.nextstrain.org/).

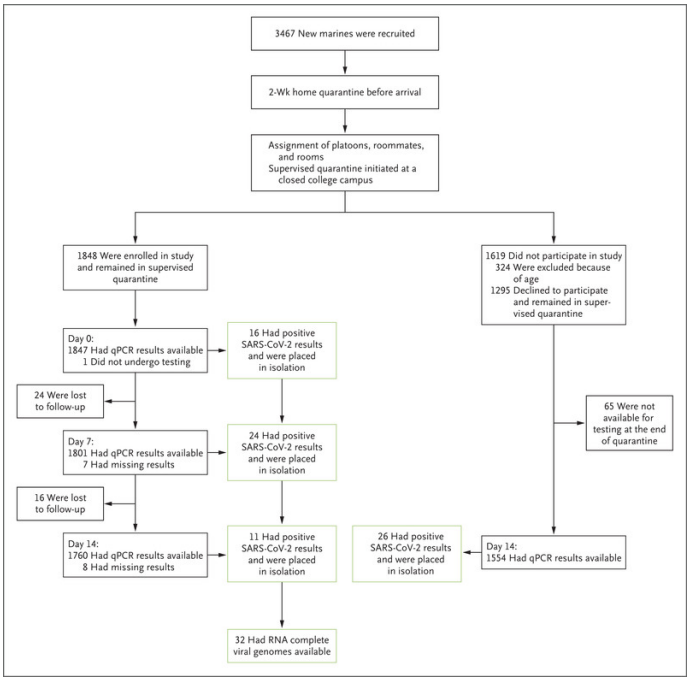
DATA ANALYSIS

The denominator for calculating the percentage of recruits who had a first positive result for SARS-CoV-2 by qPCR assay on each day of testing excluded recruits who had previously tested positive, had dropped out of the study, were administratively separated from the Marine Corps, or had missing data. The denominator for calculating the cumulative positivity rates included all recruits who had undergone testing at previous time points, including those who were no longer participating in the study. Only descriptive numerical results and percentages are reported, with no formal statistical analysis.

Results

STUDY POPULATION

Figure 1.



Study Design for SARS-CoV-2 Testing during Quarantine.

From May 12 to July 15, 2020, a total of 1848 of 3143 eligible recruits (58.8%) across nine recruit classes were enrolled in the CHARM study; 324 recruits were ineligible because they were 17 years of age. A total of 40 study participants (24 participants on day 7 and 16 participants on day 14) did not return for follow-up (Figure 1). These participants either dropped out of the study, were removed from the quarantine campus for medical or administrative reasons, or were separated from the Marine Corps. Participants were from 45 states, mostly from the eastern United States and particularly from states with larger populations. A total of 133 participants (7.2%) were born outside the United States (in 1 of 64 foreign countries), 1672 (90.5%) were male, 176 (9.5%) were female, 463 (25.1%) identified as Hispanic, and 271 (14.7%) identified as Black. The mean age of the participants was 19 years (range, 18 to 31), and 1544 (83.5%) were 18 to 20 years of age. Of the 1813 participants who underwent serologic testing at enrollment, 105 (5.8%) had serum specimens that were positive for SARS-CoV-2–specific antibodies.

Table 1.

Table 1. SARS-CoV-2 Positivity, Presence of Symptoms, and Infected Roommates.*

Variable	Day 0	Day 7	Day 14
		number/total number (percent)	
Study participants			
First positive qPCR result†	16/1847 (0.9)	24/1801 (1.3)	11/1760 (0.6)
Cumulative no. of recruits with positive qPCR results‡	16/1847 (0.9)	40/1848 (2.2)	51/1848 (2.8)
Cumulative no. of symptomatic recruits§	1/16 (6.3)	4/40 (10.0)	5/51 (9.8)
Nonparticipants¶			
Positive qPCR result	Not tested	Not tested	26/1554 (1.7)
All recruits, including study participants and nonparticipants			
Cumulative no. of recruits with positive qPCR results	16/1847 (0.9)	40/1848 (2.2)	77/3402 (2.3)
Cumulative no. of recruits with a positive roommate‖	0/16 (0.0)	4/40 (10.0)	24/77 (31.2)

* The abbreviation qPCR denotes quantitative polymerase chain reaction, and SARS-CoV-2 severe acute respiratory syndrome coronavirus 2.
† The total number on day 0 does not include 1 participant who was enrolled on day 7. The total number on day 7 includes 1 participant who was first tested on day 7 and excludes participants whose test results were missing (7 participants), who were lost to follow-up (24 participants), or who were previously positive (16 participants). The total number on day 14 includes 1 participant who was first tested on day 7 and excludes participants whose test results were missing (8 participants), who were lost to follow up (40 participants [including 24 who did not return on day 7 or day 14 and an additional 16 participants who did not return on day 14]), or who were previously positive (40 participants).
‡ The cumulative total number includes all recruits who underwent testing up to and including the relevant test day.
§ Symptomatic recruits had a fever or any symptoms within the 7 days before the positive test result. The total number is the cumulative number of study participants with positive qPCR results.
¶ Information regarding the symptoms of nonparticipants is not available. Recruits who did not participate in the study underwent testing only on day 14, as mandated by the Marine Corps. A total of 1619 recruits were categorized as nonparticipants because of ineligibility or because they declined to participate in the study. The total number of 1554 recruits on day 14 includes previous study participants who dropped out of the study but remained at the quarantine site and does not include nonparticipants who were removed from the quarantine site or separated from the Marine Corps; the number of recruits in each of these categories is not known.
‖ The number of recruits indicates the number of positive recruits with a roommate who had a first positive test on or before the given test day, and the total number is the cumulative qPCR positivity for all recruits in this category.

SARS-CoV-2 Positivity, Presence of Symptoms, and Infected Roommates.

At the time of enrollment, 16 of 1847 participants (0.9%) tested by means of qPCR were positive for SARS-CoV-2; 5 of these participants also had positive IgG serologic results (Table 1). The 16 participants with positive qPCR results reported that they had self-quarantined at home for 14 days before their arrival, had had no exposure to anyone with flulike symptoms, had had no respiratory distress or known SARS-CoV-2 infection, and had not visited a health care facility during the previous 2 weeks.

POSITIVE RESULTS AND SYMPTOMS

Of the 1801 participants who had negative qPCR results at enrollment, 24 (1.3%) were positive on day 7; of these participants, 4 had positive IgG serologic results on day 0. On day 14, a total of 11 of 1760 (0.6%) of the previously negative participants tested positive; none of these participants were seropositive on day 0. Therefore, 35 participants who had had negative qPCR results within the first 2 days after arrival at the campus became positive during the supervised quarantine. Of the 51 total participants who had at least one positive qPCR test, 22 had positive tests on more than 1 day.

Symptoms in the week before or on the day of the first positive qPCR result were reported in 5 of these 51 (9.8%) positive participants on the formal study questionnaires (Table 1). The symptoms in these 5 participants were runny nose; runny nose, chills, and cough; cough and sore throat; fever and headache; and fever, chills, sore throat, and headache. The viral load at diagnosis, estimated on the basis of the qPCR cycle threshold, was on average approximately 4 times as high in the 5 symptomatic participants as in the 46 participants who were asymptomatic (Table S2). However, some asymptomatic participants had high viral loads estimated on the basis of the cycle threshold (Fig. S1).

A total of 26 of the 1554 nonparticipants (1.7%) were found to be positive on day 14 as a result of qPCR

testing at the end of quarantine, which was mandated by the Marine Corps. A total of 24 of 77 (31.2%) infected participants and nonparticipants had an infected roommate (Table 1). All study participants and nonparticipants underwent daily screening that included temperature checks and oral reporting of symptoms; follow-up qPCR testing was performed if indicated by the surveillance check. The results of the mandated symptom screening, which was independent of the study questionnaires regarding symptoms, was not known to the study investigators; however, no recruit with SARS-CoV-2 infection was identified as a result of this clinically indicated testing. During the study period, one instructor was found to be positive in a test that was conducted as part of contact tracing related to an infected platoon member.

EPIDEMIOLOGIC ANALYSIS

To assess the epidemiologic features and transmission of SARS-CoV-2 in the context of this study, we obtained more than 95% complete viral genomes from 36 specimens obtained from 32 of 51 participants (62.7%) who had positive qPCR results for SARS-CoV-2; for 3 of these participants, genomes were recovered from samples obtained on more than one test day. Complete genomes could not be recovered from the other samples. Phylogenetic analyses that compared the recovered sequences with those recovered from patients in the United States and in other countries (a sample of 11,434 sequences) showed that most of the clades circulating in the United States were represented in SARS-CoV-2 isolates detected among recruits, a finding consistent with the geographic diversity of the participants (Fig. S2).

Table 2.

Table 2. Phylogenetic Analysis and Epidemiologically Inferred Transmission Clusters.

Phylogenetic Cluster	Sequenced Strains*	No. of Infected Recruits in the Same Platoon without Sequenced Isolate†	No. of Genomes in Cluster	No. of Infected Recruits with an Infected Roommate
	no. of strains (no. in same platoon)			
Cluster 1	2 (0)	3	5	0
Cluster 2	6 (6)	3	9	6
Cluster 3	2 (2)	0	2	2
Cluster 4	2 (2)	0	2	0
Cluster 5	5 (4)	4	9	4
Cluster 6	2 (NA)‡	0	2	0
Total	19 (14)	10	29	12

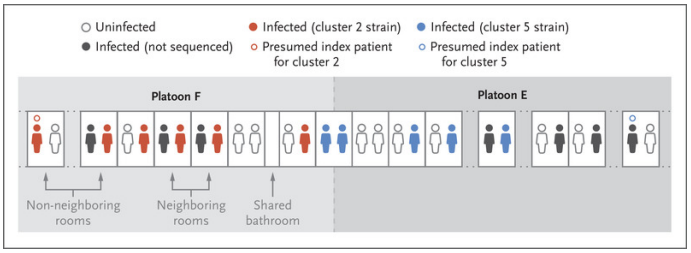
* A total of 19 genomes belonging to 6 cluster strains were obtained from 18 participants. One participant had 2 different virus strains identified in samples obtained at different times.
† Values indicate the number of infected study participants or nonparticipants who were assigned to the platoon most associated with the phylogenetically defined transmission cluster. The transmission cluster was defined according to the SARS-CoV-2 strain sequence. Infected recruits in each platoon with the highest proportion of participants infected with a sequenced cluster strain were tentatively assigned to that cluster if no sequenced isolate was obtained from that recruit.
‡ The platoon assignments of these participants were not available.

Phylogenetic Analysis and Epidemiologically Inferred Transmission Clusters.

Six independent monophyletic transmission clusters defined by distinct mutations relative to the sampled data from U.S. and global data sets were identified — a result consistent with local

transmission during the supervised quarantine. These strains were found in 18 participants; 1 participant had two different cluster strains isolated from samples obtained on different days. Two participants who had had positive qPCR results on day 0 were each infected with different cluster strains (Tables S3 and S4). Epidemiologic data showing infected roommate pairs and the relationship of cluster strains to platoon assignments supported the phylogenetic evidence for transmission of these strains at the supervised quarantine location. Among the participants infected with one of the six cluster strains of SARS-CoV-2, a total of 14 participants shared platoon assignments with other members who were in the same cluster. In addition, 10 infected recruits without sequenced SARS-CoV-2 isolates were assigned to the same platoons as the participants in transmission clusters defined by viral sequencing. There were three different clusters among six pairs of infected roommates (Table 2).

Figure 2.



Local Transmission of SARS-CoV-2 during Quarantine.

The infected participants with sequenced isolates belonging to phylogenetically identified cluster 2 or 5 had room assignments in the same hallway (Figure 2). Cluster 2 was composed of recruits in platoon F. Cluster 5 was composed of recruits in platoon E, with the exception of a single recruit in platoon F, whose roommate was an infected recruit in platoon E. Aside from this one event, we did not find evidence for transmission events across these platoons, even though recruits in each platoon were staying in rooms in the same hallway and shared a bathroom.

Discussion

We describe the results of a quarantine of nine Marine Corps recruit classes (a population of 3402 recruits) that participated in a public health mitigation program for Covid-19; recruits were under the constant supervision of Marine Corps instructors. Other settings in which young adults congregate are unlikely to reflect similar adherence to measures intended to reduce transmission. At the time of enrollment, after 2 weeks of home quarantine, approximately 1% of study participants had positive

qPCR results, and approximately 2% subsequently became infected during the 2-week supervised quarantine period.

Study participants completed a detailed symptom questionnaire on each day of the scheduled qPCR testing. Approximately 10% of the infected study participants reported that they had had symptoms during the week before a positive qPCR result or on the day that testing occurred. Independent of the study, all participants and nonparticipants underwent a daily temperature check and brief symptom screening, as mandated by the Marine Corps; follow-up clinical qPCR testing was performed only if indicated by this screening. During the supervised quarantine period, no SARS-CoV-2 infections were identified as a result of clinical testing performed because of symptom screening. All cases of infection in recruits were diagnosed as a result of the scheduled qPCR testing performed on days 0, 7, and 14 (in study participants) and on day 14 (in nonparticipants).

Viral genomes were recovered from almost two thirds of infected study participants. Phylogenetic analysis of these genomes identified six independent monophyletic transmission clusters indicative of local transmission during the supervised quarantine. Most clusters predominantly included members of the same platoon, and many infected recruits had an infected roommate. The two largest sequence-defined clusters occurred in the same class of recruits, and each cluster occurred within a platoon, with the exception of one recruit, who was roomed with an infected recruit from another platoon and was infected with a strain that belonged to the same cluster as that found in other members of that platoon. Although many infected recruits in both clusters had nearby room assignments and shared a bathroom, the epidemiologic analysis suggests that platoon membership and double-occupancy rooming were risk factors for infection, but room proximity and shared bathrooms were not (**Figure 2**).

The index patient for each cluster strain could have been a study participant, a nonparticipant among the 26 found to be infected when tested at the end of quarantine, a nonparticipant who was infected at the time of arrival on campus but cleared the virus by the end of quarantine, or other personnel. During the study, only one instructor tested positive after rapid qPCR SARS-CoV-2 testing, indicating that instructors were an unlikely source of infection. Although campus service workers cannot be excluded as sources for virus introduction, they were separated from the recruits and instructors. Overall, the recruits are the most likely source of introduction and transmission of the cluster strains.

Two recruits who had positive qPCR results on day 0 may have been the index patients for the strains involved in the two largest clusters that spread among members of their platoons. A third recruit who may have been the index patient for a cluster had a positive qPCR result on day 0, and his roommate, infected with the same strain, received a diagnosis on day 14. None of the three potential index patients

reported symptoms, which is consistent with asymptomatic transmission. We could not reconstruct the chain of infection for each cluster because complete viral genomes could not be recovered from all study participants, and samples from infected nonparticipants were unavailable for analysis. A limitation of this study is that the infection rate during the supervised quarantine period could not be estimated accurately because of possible false negative qPCR tests and because infection may have been acquired during the first self-quarantine at home or during travel to the campus but was not yet detectable on day 0 by means of qPCR assay.

Our study showed that in a group of predominantly young male military recruits, approximately 2% became positive for SARS-CoV-2, as determined by qPCR assay, during a 2-week, strictly enforced quarantine. Multiple, independent virus strain transmission clusters were identified. Shared rooms and shared platoon membership were risk factors for transmission. Most study participants with positive qPCR tests were asymptomatic, and all cases among participants and nonparticipants were identified as the result of scheduled testing rather than clinical qPCR testing performed as a result of daily screening.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

Drs. Letizia, van Bakel, and S.C. Sealfon and Drs. Ramos, Obla, Goforth, Weir, and Ge contributed equally to this article.

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Supplementary Material

Supplementary Appendix	PDF	896KB
Disclosure Forms	PDF	665KB

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Comments (2)

Dr. Prem raj P.
Dec 23, 2020

interesting case study
Molecular tools are proven handy for the rapid diagnosis of SARS-CoV-2

Dr. Prem raj P.
Dec 21, 2020

Interesting public health risk mitigation task for Covid-19
This useful case study has important implications for the effectiveness of public health measures to suppress transmission of SARS-CoV-2. This study also reveals the need for longer predeployment quarantines for preventing further transmission. Good article!!

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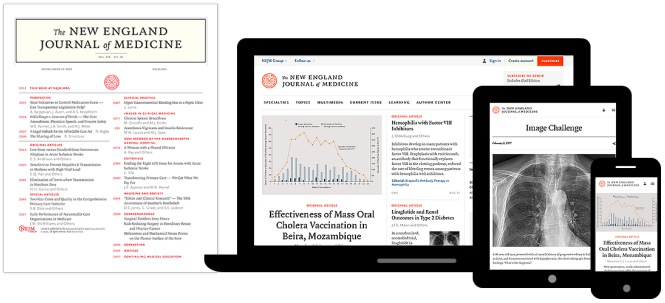

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Policy Review

Nonpharmaceutical Measures for Pandemic Influenza in Nonhealthcare Settings—Personal Protective and Environmental Measures

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Abstract

There were 3 influenza pandemics in the 20th century, and there has been 1 so far in the 21st century. Local, national, and international health authorities regularly update their plans for mitigating the next influenza pandemic in light of the latest available evidence on the effectiveness of various control measures in reducing transmission. Here, we review the evidence base on the effectiveness of nonpharmaceutical personal protective measures and environmental hygiene measures in nonhealthcare settings and discuss their potential inclusion in pandemic plans. Although mechanistic studies support the potential effect of hand hygiene or face masks, evidence from 14 randomized controlled trials of these measures did not support a substantial effect on transmission of laboratory-confirmed influenza. We similarly found limited evidence on the effectiveness of improved hygiene and environmental cleaning. We identified several major knowledge gaps requiring further research, most fundamentally an improved characterization of the modes of person-to-person transmission.

Influenza pandemics occur at irregular intervals when new strains of influenza A virus spread in humans (*1*). Influenza pandemics cause considerable health and social impact that exceeds that of typical seasonal (interpandemic) influenza epidemics. One of the characteristics of influenza pandemics is the high incidence of infections in all age groups because of the lack of population immunity. Although influenza vaccines are the cornerstone of seasonal influenza control, specific vaccines for a novel pandemic strain are not expected to be available for the first 5–6 months of the next pandemic. Antiviral drugs will be available in some locations to treat more severe infections but are unlikely to be available in the quantities that might be required to control transmission in the general community. Thus, efforts to control the next pandemic will rely largely on nonpharmaceutical interventions.

Most influenza virus infections cause mild and self-limiting disease; only a small fraction of case-patients require hospitalization. Therefore, influenza virus infections spread mainly in the community. Influenza virus is believed to be transmitted predominantly by respiratory droplets, but the size distribution of particles responsible for transmission remains unclear, and in particular, there is a lack of consensus on the role of fine particle aerosols in transmission (*2*,*3*). In healthcare settings, droplet precautions are recommended in addition to standard precautions for healthcare personnel when interacting with influenza patients and for all visitors during influenza seasons (*4*). Outside healthcare settings, hand hygiene is recommended in most national pandemic plans (*5*), and medical face masks were a common sight during the influenza pandemic in 2009. Hand hygiene has been proven to prevent many infectious diseases and might be

considered a major component in influenza pandemic plans, whether or not it has proven effectiveness against influenza virus transmission, specifically because of its potential to reduce other infections and thereby reduce pressure on healthcare services.

In this article, we review the evidence base for personal protective measures and environmental hygiene measures, and specifically the evidence for the effectiveness of these measures in reducing transmission of laboratory-confirmed influenza in the community. We also discuss the implications of the evidence base for inclusion of these measures in pandemic plans.

Methods and Results

We conducted systematic reviews to evaluate the effectiveness of personal protective measures on influenza virus transmission, including hand hygiene, respiratory etiquette, and face masks, and a systematic review of surface and object cleaning as an environmental measure (Table 1). We searched 4 databases (Medline, PubMed, EMBASE, and CENTRAL) for literature in all languages. We aimed to identify randomized controlled trials (RCTs) of each measure for laboratory-confirmed influenza outcomes for each of the measures because RCTs provide the highest quality of evidence. For respiratory etiquette and surface and object cleaning, because of a lack of RCTs for laboratory-confirmed influenza, we also searched for RCTs reporting effects of these interventions on influenza-like illness (ILI) and respiratory illness outcomes and then for observational studies on laboratory-confirmed influenza, ILI, and respiratory illness outcomes. For each review, 2 authors (E.Y.C.S. and J.X.) screened titles and abstracts and reviewed full texts independently.

We performed meta-analysis for hand hygiene and face mask interventions and estimated the effect of these measures on laboratory-confirmed influenza prevention by risk ratios (RRs). We used a fixed-effects model to estimate the overall effect in a pooled analysis or subgroup analysis. No overall effect would be generated if there was considerable heterogeneity on the basis of I^2 statistic ≥75% (*6*). We performed quality assessment of evidence on hand hygiene and face mask interventions by using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach (*7*). We provide additional details of the search strategies, selection of articles, summaries of the selected articles, and quality assessment (Appendix).

Personal Protective Measures

Hand Hygiene

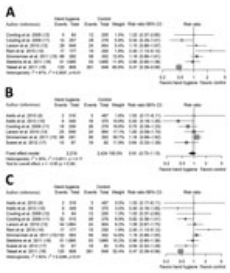

Figure 1. Meta-analysis of risk ratios for the effect of hand hygiene with or without face mask use on laboratory-confirmed influenza from 10 randomized controlled trials with >11,000 participants. A) Hand hygiene alone;...

We identified a recent systematic review by Wong et al. on RCTs designed to assess the efficacy of hand hygiene interventions against transmission of laboratory-confirmed influenza (*8*). We used this review as a starting point and then searched for additional literature published after 2013; we found 3 additional eligible articles published during the search

period of January 1, 2013–August 13, 2018. In total, we identified 12 articles (*9*–*20*), of which 3 articles were from the updated search and 9 articles from Wong et al. (*8*). Two articles relied on the same underlying dataset (*16*,*19*); therefore, we counted these 2 articles as 1 study, which resulted in 11 RCTs. We further selected 10 studies with >10,000 participants for inclusion in the meta-analysis (Figure 1). We excluded 1 study from the meta-analysis because it provided estimates of infection risks only at the household level, not the individual level (*20*). We did not generate an overall pooled effect of hand hygiene only or of hand hygiene with or without face mask because of high heterogeneity in individual estimates (I^2 87 and 82%, respectively). The effect of hand hygiene combined with face masks on laboratory-confirmed influenza was not statistically significant (RR 0.91, 95% CI 0.73–1.13; I^2 = 35%, p = 0.39). Some studies reported being underpowered because of limited sample size, and low adherence to hand hygiene interventions was observed in some studies.

We further analyzed the effect of hand hygiene by setting because transmission routes might vary in different settings. We found 6 studies in household settings examining the effect of hand hygiene with or without face masks, but the overall pooled effect was not statistically significant (RR 1.05, 95% CI 0.86–1.27; I^2 = 57%, p = 0.65) (Appendix Figure 4) (*11*–*15*,*17*). The findings of 2 studies in school settings were different (Appendix Figure 5). A study conducted in the United States (*16*) showed no major effect of hand hygiene, whereas a study in Egypt (*18*) reported that hand hygiene reduced the risk for influenza by >50%. A pooled analysis of 2 studies in university residential halls reported a marginally significant protective effect of a combination of hand hygiene plus face masks worn by all residents (RR 0.48, 95% CI 0.21–1.08; I^2 = 0%, p = 0.08) (Appendix Figure 6) (*9*,*10*).

In support of hand hygiene as an effective measure, experimental studies have reported that influenza virus could survive on human hands for a short time and could transmit between hands and contaminated surfaces (*2*,*21*). Some field studies reported that influenza A(H1N1)pdm09 and influenza A(H3N2) virus RNA and viable influenza virus could be detected on the hands of persons with laboratory-confirmed influenza (*22*,*23*), supporting the potential of direct and indirect contact transmission to play a role in the spread of influenza. Other experimental studies also demonstrated that hand hygiene could reduce or remove infectious influenza virus from human hands (*24*,*25*). However, results from our meta-analysis on RCTs did not provide evidence to support a protective effect of hand hygiene against transmission of laboratory-confirmed influenza. One study did report a major effect, but in this trial of hand hygiene in schools in Egypt, running water had to be installed and soap and hand-drying material had to be introduced into the intervention schools as part of the project (*18*). Therefore, the impact of hand hygiene might also be a reflection of the introduction of soap and running water into primary schools in a lower-income setting. If one considers all of the evidence from RCTs together, it is useful to note that some studies might have underestimated the true effect of hand hygiene because of the complexity of implementing these intervention studies. For instance, the control group would not typically have zero knowledge or use of hand hygiene, and the intervention group might not adhere to optimal hand hygiene practices (*11*,*13*,*15*).

Hand hygiene is also effective in preventing other infectious diseases, including diarrheal diseases and some respiratory diseases (*8*,*26*). The need for hand hygiene in disease prevention is well recognized among most communities. Hand hygiene has been accepted as a personal protective measure in >50% of national preparedness plans for pandemic influenza (*5*). Hand hygiene practice is commonly performed with soap and water, alcohol-based hand rub, or other waterless hand disinfectants, all of which are easily accessible, available, affordable, and well accepted in most communities. However, resource limitations in some areas are a concern when clean running water or alcohol-based hand rub are not available. There are few adverse effects of hand hygiene except for skin irritation caused by some hand hygiene products (*27*). However, because of certain social or religious practices, alcohol-based hand sanitizers might not be permitted in some locations (*28*). Compliance with proper hand hygiene practice tends to be low because habitual behaviors are difficult to change (*29*). Therefore, hand hygiene promotion programs are needed to advocate and encourage proper and effective hand hygiene.

Respiratory Etiquette

Respiratory etiquette is defined as covering the nose and mouth with a tissue or a mask (but not a hand) when coughing or sneezing, followed by proper disposal of used tissues, and proper hand hygiene after contact with respiratory secretions (*30*). Other descriptions of this measure have included turning the head and covering the mouth when coughing and coughing or sneezing into a sleeve or elbow, rather than a hand. The rationale for not coughing into hands is to prevent subsequent contamination of other surfaces or objects (*31*). We conducted a search on November 6, 2018, and identified literature that was available in the databases during 1946–November 5, 2018. We did not identify any published research on the effectiveness of respiratory etiquette in reducing the risk for laboratory-confirmed influenza or ILI. One observational study reported a similar incidence rate of self-reported respiratory illness (defined by ≥1 symptoms: cough, congestion, sore throat, sneezing, or breathing problems) among US pilgrims with or without practicing respiratory etiquette during the Hajj (*32*). The authors did not specify the type of respiratory etiquette used by participants in the study. A laboratory-based study reported that common respiratory etiquette, including covering the mouth by hands, tissue, or sleeve/arm, was fairly ineffective in blocking the release and dispersion of droplets into the surrounding environment on the basis of measurement of emitted droplets with a laser diffraction system (*31*).

Respiratory etiquette is often listed as a preventive measure for respiratory infections. However, there is a lack of scientific evidence to support this measure. Whether respiratory etiquette is an effective nonpharmaceutical intervention in preventing influenza virus transmission remains questionable, and worthy of further research.

Face Masks

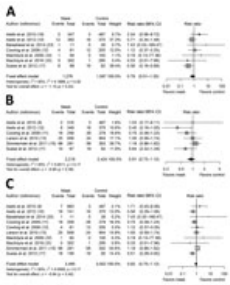

Figure 2. Meta-analysis of risk ratios for the effect of face mask use with or without enhanced hand hygiene on laboratory-confirmed influenza from 10 randomized controlled trials with >6,500 participants. A) Face mask...

In our systematic review, we identified 10 RCTs that reported estimates of the effectiveness of face masks in reducing laboratory-confirmed influenza virus infections in the community from literature published during 1946–July 27, 2018. In pooled analysis, we found no significant reduction in influenza transmission with the use of face masks (RR 0.78, 95% CI 0.51–1.20; I^2 = 30%, p = 0.25) (Figure 2). One study evaluated the use of masks among pilgrims from Australia during the Hajj pilgrimage and reported no major difference in the risk for laboratory-confirmed influenza virus infection in the control or mask group (*33*). Two studies in university settings assessed the effectiveness of face masks for primary protection by monitoring the incidence of laboratory-confirmed influenza among student hall residents for 5 months (*9*,*10*). The overall reduction in ILI or laboratory-confirmed influenza cases in the face mask group was not significant in either studies (*9*,*10*). Study designs in the 7 household studies were slightly different: 1 study provided face masks and P2 respirators for household contacts only (*34*), another study evaluated face mask use as a source control for infected persons only (*35*), and the remaining studies provided masks for the infected persons as well as their close contacts (*11*–*13*,*15*,*17*). None of the household studies reported a significant reduction in secondary laboratory-confirmed influenza virus infections in the face mask group (*11*–*13*,*15*,*17*,*34*,*35*). Most studies were underpowered because of limited sample size, and some studies also reported suboptimal adherence in the face mask group.

Disposable medical masks (also known as surgical masks) are loose-fitting devices that were designed to be worn by medical personnel to protect accidental contamination of patient wounds, and to protect the wearer against splashes or sprays of bodily fluids (*36*). There is limited evidence for their effectiveness in preventing influenza virus transmission either when worn by the infected person for source control or when worn by uninfected persons to reduce exposure. Our systematic review found no significant effect of face masks on transmission of laboratory-confirmed influenza.

We did not consider the use of respirators in the community. Respirators are tight-fitting masks that can protect the wearer from fine particles (*37*) and should provide better protection against influenza virus exposures when properly worn because of higher filtration efficiency. However, respirators, such as N95 and P2 masks, work best when they are fit-tested, and these masks will be in limited supply during the next pandemic. These specialist devices should be reserved for use in healthcare settings or in special subpopulations such as immunocompromised persons in the community, first responders, and those performing other critical community functions, as supplies permit.

In lower-income settings, it is more likely that reusable cloth masks will be used rather than disposable medical masks because of cost and availability (*38*). There are still few uncertainties in the practice of face mask use, such as who should wear the mask and how long it should be used for. In theory, transmission should be reduced the most if both infected members and other contacts wear masks, but compliance in uninfected close contacts could be a problem (*12*,*34*). Proper use of face masks is essential because improper use might increase the risk for transmission (*39*). Thus, education on the proper use and disposal of used face masks, including hand hygiene, is also needed.

Environmental Measures

Surface and Object Cleaning

For the search period from 1946 through October 14, 2018, we identified 2 RCTs and 1 observational study about surface and object cleaning measures for inclusion in our systematic review (*40*–*42*). One RCT conducted in day care nurseries found that biweekly cleaning and disinfection of toys and linen reduced the detection of multiple viruses, including adenovirus, rhinovirus, and respiratory syncytial virus in the environment, but this intervention was not significant in reducing detection of influenza virus, and it had no major protective effect on acute respiratory illness (*41*). Another RCT found that hand hygiene with hand sanitizer together with surface disinfection reduced absenteeism related to gastrointestinal illness in elementary schools, but there was no major reduction in absenteeism related to respiratory illness (*42*). A cross-sectional study found that passive contact with bleach was associated with a major increase in self-reported influenza (*40*).

Given that influenza virus can survive on some surfaces for prolonged periods (*43*), and that cleaning or disinfection procedures can effectively reduce or inactivate influenza virus from surfaces and objects in experimental studies (*44*), there is a theoretical basis to believe that environmental cleaning could reduce influenza transmission. As an illustration of this proposal, a modeling study estimated that cleaning of extensively touched surfaces could reduce influenza A infection by 2% (*45*). However, most studies of influenza virus in the environment are based on detection of virus RNA by PCR, and few studies reported detection of viable virus.

Although we found no evidence that surface and object cleaning could reduce influenza transmission, this measure does have an established impact on prevention of other infectious diseases (*42*). It should be feasible to implement this measure in most settings, subject to the availability of water and cleaning products. Although irritation caused by cleaning products is limited, safety remains a concern because some cleaning products can be toxic or cause allergies (*40*).

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Discussion

In this review, we did not find evidence to support a protective effect of personal protective measures or environmental measures in reducing influenza transmission. Although these measures have mechanistic support based on our knowledge of how influenza is transmitted from person to person, randomized trials of hand hygiene and face masks have not demonstrated protection against laboratory-confirmed influenza, with 1 exception (*18*). We identified only 2 RCTs on environmental cleaning and no RCTs on cough etiquette.

Hand hygiene is a widely used intervention and has been shown to effectively reduce the transmission of gastrointestinal infections and respiratory infections (*26*). However, in our systematic review, updating the findings of Wong et al. (*8*), we did not find evidence of a major effect of hand hygiene on laboratory-confirmed influenza virus transmission (Figure 1). Nevertheless, hand hygiene might be included in influenza pandemic plans as part of general hygiene and infection prevention.

We did not find evidence that surgical-type face masks are effective in reducing laboratory-confirmed influenza transmission, either when worn by infected persons (source control) or by persons in the general community to reduce their susceptibility (Figure 2). However, as with hand hygiene, face masks might be able to reduce the transmission of other infections and therefore have value in an influenza pandemic when healthcare resources are stretched.

It is essential to note that the mechanisms of person-to-person transmission in the community have not been fully determined. Controversy remains over the role of transmission through fine-particle aerosols (*3*,*46*). Transmission by indirect contact requires transfer of viable virus from respiratory mucosa onto hands and other surfaces, survival on those surfaces, and successful inoculation into the respiratory mucosa of another person. All of these components of the transmission route have not been studied extensively. The impact of environmental factors, such as temperature and humidity, on influenza transmission is also uncertain (*47*). These uncertainties over basic transmission modes and mechanisms hinder the optimization of control measures.

In this review, we focused on 3 personal protective measures and 1 environmental measure. Other potential environmental measures include humidification in dry environments (*48*), increasing ventilation (*49*), and use of upper-room UV light (*50*), but there is limited evidence to support these measures. Further investigations on the effectiveness of respiratory etiquette and surface cleaning through conducting RCTs would be helpful to provide evidence with higher quality; evaluation of the effectiveness of these measures targeting specific population groups, such as immunocompromised persons, would also be beneficial (Table 2). Future cost-effectiveness evaluations could provide more support for the potential use of these measures. Further research on transmission modes and alternative interventions to reduce influenza transmission would be valuable in improving pandemic preparedness. Finally, although our review focused on nonpharmaceutical measures to be taken during influenza pandemics, the findings could also apply to severe seasonal influenza epidemics. Evidence from RCTs of hand hygiene or face masks did not support a substantial effect on transmission of laboratory-confirmed influenza, and limited evidence was available on other environmental measures.

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Ms. Xiao is a postgraduate student at the School of Public Health, University of Hong Kong, Hong Kong, China. Her primary research interests are influenza epidemiology and the dynamics of person-to-person transmission.

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Exhibit F

GLOBAL INFLUENZA PROGRAMME

Non-pharmaceutical public health measures for mitigating the risk and impact of epidemic and pandemic influenza

Annex: Report of systematic literature reviews

World Health Organization

Table 35. Quality of evidence and summary of results for each NPI

MEASURES	QUALITY OF EVIDENCE		RESULTS
1. Hand hygiene	Moderate (lack of effectiveness in reducing influenza transmission)		Eleven RCTs were included in this review. While hand hygiene was not effective against laboratory-confirmed influenza in meta-analysis in community settings and university halls, it was effective in one of two trials conducted in schools.
2. Respiratory etiquette	None		No scientific studies were identified for inclusion in this review.
3. Face masks	Moderate (lack of effectiveness in reducing influenza transmission)		Ten RCTs were included in meta-analysis, and there was no evidence that face masks are effective in reducing transmission of laboratory-confirmed influenza.
4. Surface and object cleaning	Low (lack of effectiveness in reducing influenza transmission)		Two RCTs and one cross-sectional study were included in the systematic review. There was evidence that surface and object cleaning could reduce detections of virus in the environment, but there was no evidence of effectiveness against laboratory-confirmed influenza virus infection.
5. Other environmental measures	**UV light**	None	No scientific studies were identified for inclusion in this review.
	Ventilation	Very low (effective)	In simulation studies, increasing the ventilation rate reduced influenza transmission.
	Humidity	None	No scientific studies were identified for inclusion in this review.
6. Contact tracing	Very low (unknown)		Evidence for overall effectiveness of contact tracing was limited. All included studies were simulation models. Only one study suggested the benefit of adding contact tracing on top of isolation and quarantine. Such addition was estimated to provide at most modest benefit, at the same time this would considerably increase the number of quarantined individuals.

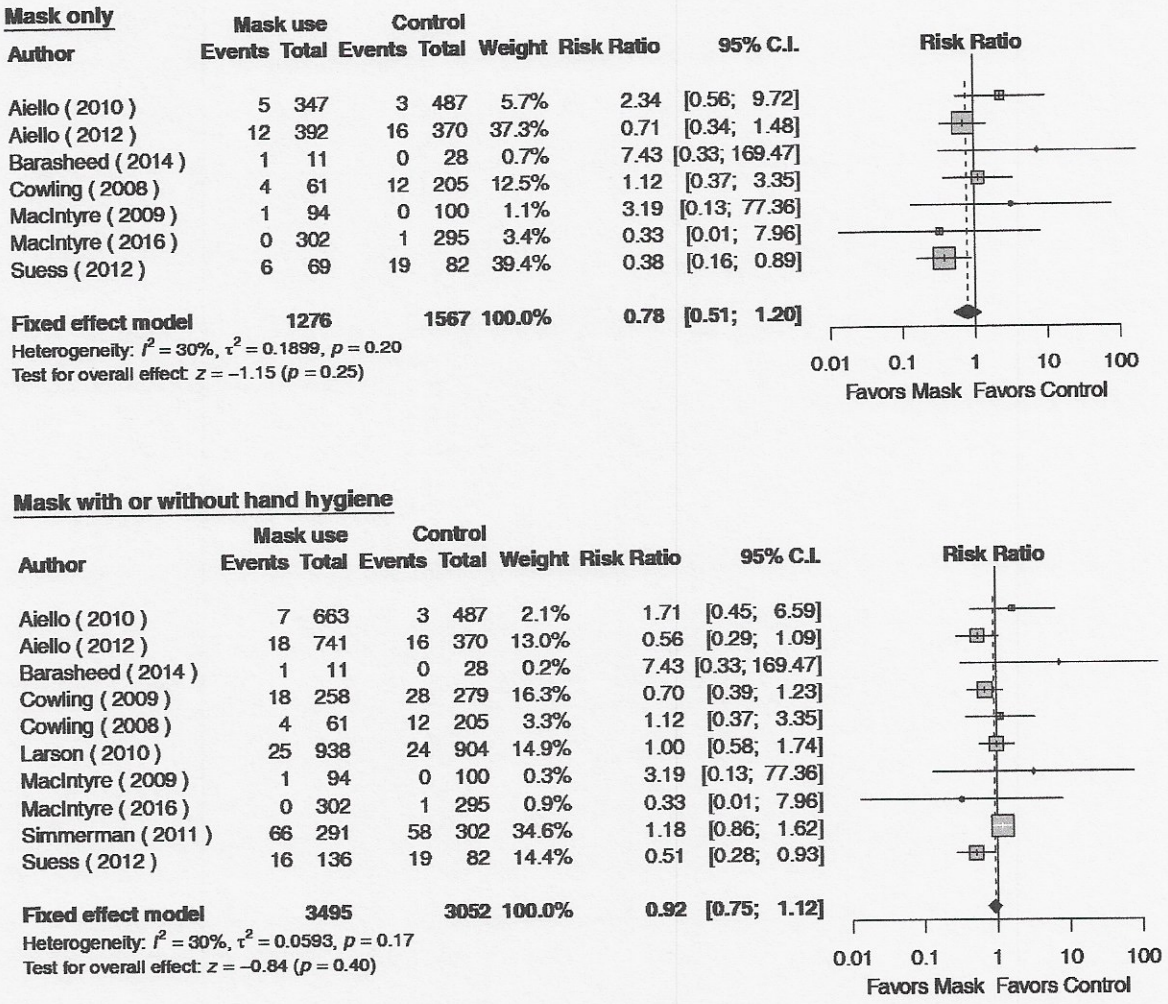

Fig. 10. Effects of face mask use interventions with or without enhanced hand hygiene on laboratory-confirmed influenza in 10 studies

Ethical considerations

No major ethical considerations. Masks may be more culturally acceptable in some locations than others, and a variety of factors may affect compliance.

Knowledge gaps

In the studies of face mask use with or without hand hygiene, the pooled estimate of the risk reduction against laboratory-confirmed influenza was 0.90 (95% CI: 0.75–1.12), which suggests that additional randomized trials would be less likely to identify a substantial protective efficacy of face masks. However, the majority of these studies were conducted in households in which at least one person was infected, and exposure levels might be relatively higher. Additional studies of face mask use in the general community would be valuable. While respirators should provide better protection against respiratory infections compared to face masks because of their higher filtration efficiency, a household randomized controlled study showed no difference in their effect on ILIs and laboratory-confirmed influenza virus infection (*48*). One issue is that respirators require fit testing for optimal performance, but fit testing facilities are not widely available in the community.

influenza virus infections in contacts in the face mask arms, and some studies reported that low compliance of the use of NPIs could affect the results (*21*). One study reported a significant reduction in laboratory-confirmed influenza virus infections in contacts in the face mask and hand hygiene group in the subset of households where the intervention was applied within 36 hours of symptom onset in the index case (*24*).

Ten studies were pooled to conduct a meta-analysis to quantify the efficacy of community based use of face masks in the reduction of laboratory-confirmed influenza virus infection (Table 7). In the pooled analysis, there was a non-significant relative risk reduction of 22% (RR = 0.78, 95% CI: 0.51–1.20, I2 = 30%, p = 0.25) in the face mask group and 8% in the face mask group regardless of the addition of practice of hand hygiene (RR = 0.92, 95% CI: 0.75–1.12, I2 = 30%, p = 0.40). The evidence profile for face masks outcome is summarized in Table 8.

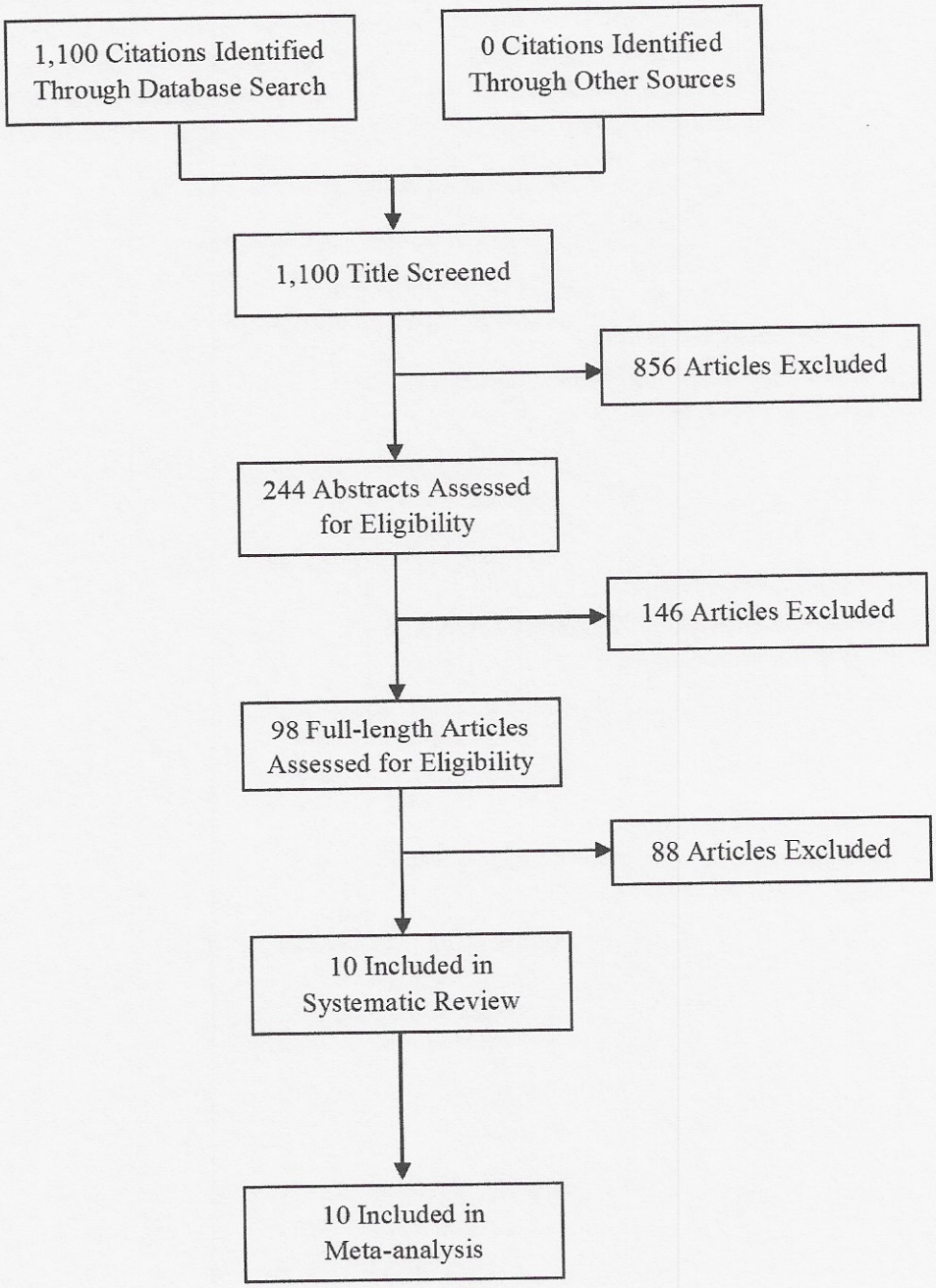

Fig. 9. The flow chart of the process and results of study selection

Exhibit G

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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Volume 15, Number 2—February 2009

CME ACTIVITY - *Research*

Face Mask Use and Control of Respiratory Virus Transmission in Households

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Introduction

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Learning Objectives

Upon completion of this activity, participants will be able to:

- List the nonpharmaceutical strategies that have been examined for respiratory infection control.
- Describe the type of study used to compare the use of face masks with no face masks for respiratory infection control.
- Identify the most frequent viral cause of influenza-like respiratory infection in children.
- Describe adherence to face mask use by adult household contacts of children with viral respiratory infection.
- Describe the efficacy of face mask use for preventing spread of influenza-like infection.

Editor

Beverly Merritt, Technical Writer-Editor, *Emerging Infectious Diseases. Disclosure: Beverly Merritt has disclosed no relevant financial relationships.*

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Abstract

Many countries are stockpiling face masks for use as a nonpharmaceutical intervention to control virus transmission during an influenza pandemic. We conducted a prospective cluster-randomized trial comparing surgical masks, non–fit-tested P2 masks, and no masks in prevention of influenza-like illness (ILI) in households. Mask use adherence was self-reported. During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. We found that adherence to mask use significantly reduced the risk for ILI-associated infection, but <50% of participants wore masks most of the time. We concluded that household use of face masks is associated with low adherence and is ineffective for controlling seasonal respiratory disease. However, during a severe pandemic when use of face masks might be greater, pandemic transmission in households could be reduced. Many countries are stockpiling face masks for use as nonpharmaceutical interventions to reduce viral transmission during an influenza pandemic. We conducted a prospective cluster-randomized trial comparing surgical masks, non–fit-tested P2 masks, and no masks in prevention of influenza-like illness (ILI) in households. During the 2006 and 2007 winter seasons, 286 exposed adults from 143 households who had been exposed to a child with clinical respiratory illness were recruited. Intent-to-treat analysis showed no significant difference in the relative risk of ILI in the mask use groups compared with the control group; however, <50% of those in the mask use groups reported wearing masks most of the time. Adherence to mask use was associated with a significantly reduced risk of ILI-associated infection. We concluded that household use of masks is associated with low adherence and is ineffective in controlling seasonal ILI. If adherence were greater, mask use might reduce transmission during a severe influenza pandemic.

Highly pathogenic avian influenza virus A (H5N1) continues to spread globally, posing a serious human pandemic threat. In the event of an influenza pandemic or other emerging respiratory disease such as severe acute respiratory syndrome (SARS), it is likely that antiviral drugs and vaccines will be in short supply or that delivery could be delayed. Therefore, nonpharmaceutical interventions such as mask use, handwashing, and other hygiene measures or school closure might be effective early control strategies. In contrast to pharmaceutical interventions, little is known about the effectiveness of nonpharmaceutical interventions in the community. A recent analysis gives estimates of the effect of school closure (*1*), and several prospective, randomized controlled trials of handwashing have been published (*2*–*11*). However, clinical trial data on the ability of face masks to reduce respiratory virus transmission in the community are limited to 1 published prospective trial, which showed lack of efficacy (*12*). In addition, adverse effects of wearing masks (particularly respirators) may affect compliance and effectiveness (*13*–*15*). Despite the lack of quantitative evidence, many countries have included recommendations in their pandemic plans on the use of face masks (*16*–*18*). We present the results of a cluster-randomized household study of the effectiveness of using face masks to prevent or reduce transmission of influenza-like illness (ILI).

Methods

A prospective, cluster-randomized trial of mask use in households was conducted during the 2 winter seasons of 2006 and 2007 (August to the end of October 2006 and June to the end of October 2007) in Sydney, Australia. Enrollment in the study was restricted to households with ≥2 healthy adults ≥16 years of age; the adults had known exposure within the household to a child with fever and respiratory symptoms. Suitable households were identified at a pediatric health service comprising the emergency department of a pediatric hospital and a pediatric primary care practice in Sydney, New South Wales, Australia. The study protocol was approved by the local institutional review board.

Randomization and Intervention

Participating households were randomized to 1 of 3 arms by a secure computerized randomization process: 1) surgical

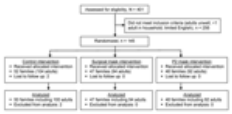

Figure 1. . . Flow diagram of recruitment for the prospective cluster-randomized trial, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

masks (3M surgical mask, catalogue no. 1820; St. Paul, MN, USA) for 2 adults, to be worn at all times when in the same room as the index child, regardless of the distance from the child; 2) P2 masks (3M flat-fold P2 mask, catalogue no. 9320; Bracknell, Berkshire, UK), for 2 adults, to be worn at all times when in the same room as the index child, regardless of the distance from the child; and 3) a control group (no masks used). The P2 masks used have an almost identical specification as N95 masks used in the United States (*19*). According to New South Wales Health guidelines, pamphlets about infection control were provided to participants in all arms. Study participants and trial staff were not blinded, as it is not technically possible to blind the mask type to which participants were randomized. However, laboratory staff were blinded to the arm of randomization. Figure 1 shows the flow diagram for the trial as suggested by CONSORT guidelines (*20*).

Recruitment and Follow-up

Children 0–15 years of age seeking treatment at pediatric health services with fever (temperature >37.8°C) and either cough or sore throat were identified by an electronic triage system. Parents or primary caregivers were approached in the waiting room, and that household was invited to join the study if all of the following criteria were satisfied: 1) the household contained ≥2 adults ≥16 years of age and 1 child 0–15 years of age; 2) the index child had fever (temperature >37.8°C) and either a cough or sore throat; 3) the child was the first and only person to become ill in the family in the previous 2 weeks; 4) adult caregivers consented to participate in the study; and 5) the index child was not admitted to the hospital.

If eligibility criteria were satisfied, adults from the household were enrolled in the study. Enrolled adults and any siblings of the index child were then evaluated for respiratory symptoms and signs (fever, history of fever or feeling feverish in the past week, myalgia, arthralgia, sore throat, cough, sneezing, runny nose, nasal congestion, headache). If any of these symptoms were present, the family and household were excluded. Sociodemographic and medical information including influenza vaccination history (both the index child and participating adults) was obtained using a researcher-administered questionnaire. Medication use was also recorded. The index case-patient had combined nasal (each nostril) and throat swabs collected for multiplex reverse transcription–PCR (RT-PCR) testing. The household was randomized to 1 of the 3 arms, allocated the appropriate mask type, and educated about infection prevention. Formal fit testing of the P2 masks was not performed, but information pertaining to the correct method for fitting and disposing of the masks was provided. Over the next week, participants were contacted by telephone daily to determine if symptoms had developed and to record adherence to mask use throughout the day.

Each household was supplied with a thermometer to measure the temperature of symptomatic adult participants twice daily. If study staff determined that a participant had developed respiratory disease symptoms at follow-up, a home visit was conducted on the same day and the participant was swabbed and tested for respiratory viruses (see methods described below). Symptomatic participants were then followed up daily for 2 weeks.

Because all respiratory pathogens share similar transmission mechanisms—aerosol, droplet, and fomite spread (although the relative role of these factors may vary among different viruses and in different clinical situations)—we deliberately considered a broad definition of clinical cases consistent with a wide range of common respiratory viruses.

Respiratory viruses detected in the study included influenza A and B, respiratory syncytial virus (RSV), adenovirus, parainfluenza viruses (PIV) types 1–3, coronaviruses 229E and OC43, human metapneumovirus (hMPV), enteroviruses, and rhinoviruses.

Adherence to face mask use was specifically monitored during each household follow-up. Measuring adherence and reasons for nonadherence is critical for evaluating the efficacy of mask use for reducing treatment and for providing practical advice on future use of face masks. Exit interviews with participants in the surgical mask and the P2 mask arms were conducted to gain further insights into adherence.

Sample Collection and Laboratory Testing

Rayon-tipped, plastic-shafted swabs were inserted separately into each participant's nostrils and pharynx, placed into viral transport media, and transported immediately to the laboratory or stored at 4°C if transport was delayed. Nose and throat swabs of index children and adult participants with symptoms of respiratory illness were tested by using nucleic acid and a series of multiplex RT-PCR tests (*21*) to detect influenza A and B and RSV, PIV types 1–3, picornaviruses (enteroviruses or rhinoviruses), adenoviruses, coronaviruses 229E and OC43, and hMPV.

Case Definition

To include the broadest possible spectrum of clinical syndromes occurring among enrolled adults (*22*), during follow-up we defined ILI by the presence of fever (temperature >37.8°C), feeling feverish or a history of fever, ≥2 symptoms (sore throat, cough, sneezing, runny nose, nasal congestion, headache), or 1 of the symptoms listed plus laboratory confirmation of respiratory viral infection. The choice of a relatively broad clinical case definition was dictated by our interest in interrupting transmission of a broad range of respiratory viruses. Laboratory-confirmed cases during the follow-up were defined by the presence of ≥1 of the symptoms listed above plus laboratory detection of a respiratory virus.

Study Outcomes and Analysis

The primary study outcomes in enrolled adults were the presence of ILI or a laboratory diagnosis of respiratory virus infection within 1 week of enrollment. Given that we demonstrated some dual infections and that there may be a variable sensitivity of RT-PCR for different respiratory viruses, we included all incident infections in adults (by clinical case definition and laboratory testing) in the analysis. We also measured the time from recruitment to infection. Causal linking of the outcomes of ILI and adherence to use of face masks required consideration of the timing of both.

Analysis of primary outcomes was by intention to treat. We performed a multivariate Cox proportional-hazards survival analysis to study secondary outcomes and determine how time lag from recruitment to infection of a secondary case-patient was affected by explanatory covariates (*23*). Gaussian random effects were incorporated in the model to account for the natural clustering of persons in households (*24*). The day of infection was reconstructed from the day of symptom onset under the assumption that the incubation period was 1–2 days. To account for exposures that occurred before recruitment, the time when survival analysis started was defined as the maximum value between the day of recruitment minus the incubation period and the start of illness in the index case. (For example, assume a household recruited on day 0 and an incubation period of 2 days. If illness in the index case began on day –3, then the survival analysis began on day –2; if illness in the index case began on day –1, then the survival analysis began the same day.)

The following variables were included in the models: daily adherence to use of P2 or surgical masks, number of adults in the household, number of siblings in the household, and index case ≤5 years of age. This analysis was performed using the survival package of the statistical software R (www.r-project.org). Comparisons among groups were made with the Fisher exact test for categorical variables. A 2-sided p value ≤0.05 was considered significant.

Power Analysis

Assuming a secondary attack rate in exposed adults of 20% and an intraclass correlation coefficient of 30%, we estimated that 94 adults would be needed in each arm of the study to show efficacy of ≥75% of P2 or surgical masks at 80% power and with a p value of 0.05. Our efficacy estimate was a conservative assumption based on observational data for the combined effects of all mask types during the SARS epidemic in Hong Kong (*25*).

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Results

Study Population

We recruited 290 adults from 145 families; 47 households (94 enrolled adults and 180 children) were randomized to the surgical mask group, 46 (92 enrolled adults and 172 children) to the P2 mask group, and 52 (104 enrolled adults and 192 children) to the no-mask (control) group. Two families in the control group were lost to follow-up during the study. Characteristics of the families who participated are shown in Table 1, with no significant differences noted among the 3 arms.

Samples were collected from 141 children; respiratory viruses were detected in 90 (63.8%) children. In 79 (56.0%) of 141 cases, a single pathogen was detected: influenza A in 19/141 (13.5%); influenza B in 7/141 (4.9%); adenoviruses in 7/141 (4.9%); RSV in 5/141 (3.5%); PIV in 8/141 (5.5%) (PIV-1 in 1/141 [0.70%]; PIV-2 in 2/141 [1.4%]; PIV-3 in 5/141 [3.5%]); hMPV in 8/141 (5.7%); and coronavirus OC43 in 3/141 (2.1%). Other viruses detected included picornaviruses in 22/141 (15.6%): rhinoviruses in 11/22 (50.0%); enteroviruses in 5/22 (22.7%) (enterovirus 68 in 1/5 [20.0%] and others in 4/5 [80.0%]); and uncharacterized nonsequenced picornaviruses in 6/22 (27.0%). An additional 11 children (7.8%) had dual or co-infection: 4 (2.8%) with adenovirus and rhinovirus, 2 (1.4%) with rhinovirus and coronavirus; and 1 each with influenza A and enterovirus, influenza A and PIV-2, influenza A and rhinovirus, RSV and enterovirus, and adenovirus and hMPV.

Adherence

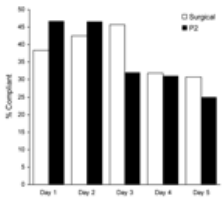

Figure 2. . . Compliance with mask use by day over 5 consecutive days during the study, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

Characteristics of the adherent versus nonadherent participants who were recruited are shown in Table 2; no significant differences were noted between the 2 groups except for the presence of ≥3 adults in the household. On day 1 of mask use, 36 (38%) of the 94 surgical mask users and 42 (46%) of the 92 P2 mask users stated that they were wearing the mask

"most or all" of the time. Other participants were wearing face masks rarely or never. The difference between the groups was not significant (p = 0.37). Adherence dropped to 29/94 (31%) and 23/92 (25%), respectively, by day 5 of mask use (Figure 2).

Table 3 shows reported problems with mask use. There were no significant differences in difficulties with mask use between the P2 and surgical mask groups, but ≥50% reported concerns, the main one being that wearing a face mask was uncomfortable. Other concerns were that the child did not want the parent wearing a mask and the parent forgot to wear the mask. Additional comments made by some included that the mask did not fit well and that it was not practical to wear at meal time or while asleep. Some adults wore the mask during the day but not at night, even though the sick child was sleeping beside them in their bed.

Intention-to-Treat Analysis

ILI was reported in 21/94 (22.3%) in the surgical group, 14/92 (15.2%) in the P2 group, and 16/100 (16.0%) in the control group, respectively. Samples were collected from 43/51 (84%) sick adults, with respiratory viruses isolated in 17/43 (40%) sick adults. Viral pathogens were isolated from 6/94 (6.4%) in the surgical mask group, 8/92 (8.7%) in the P2 group, and 3/100 (3.0%) in the control group. In 10/17 laboratory-positive cases, the same respiratory virus was isolated in the adult and the child (surgical, 3/94; P2 group, 5/92; and control, 2/100). In 2 cases, the adult was the only person with a laboratory-confirmed virus (1 each from the P2 and surgical groups); in the remaining 5 adults, the virus detected in the child differed from that in the adult (surgical, 2; P2 group, 2; and control group, 1). No dual infections were detected in the adults. Intention-to-treat analysis by households and by participants showed no significant difference between the groups (Table 4).

Risk Factors for ILI

Under the assumption that the incubation period is equal to 1 day (the most probable value for the 2 most common viruses isolated, influenza [*21*] and rhinovirus [*26*]), adherent use of P2 or surgical masks significantly reduces the risk for ILI infection, with a hazard ratio equal to 0.26 (95% CI [confidence interval] 0.09–0.77; p = 0.015). No other covariate was significant. Under the less likely assumption that the incubation period is equal to 2 days, the quantified effect of complying with P2 or surgical mask use remains strong, although borderline significant; hazard ratio was 0.32 (95% CI 0.11–0.98; p = 0.046). The study was underpowered to determine if there was a difference in efficacy between P2 and surgical masks (Table 5).

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Discussion

We present the results of a prospective clinical trial of face mask use conducted in response to an urgent need to clarify the clinical benefit of using masks. The key findings are that ≤50% of participants were adherent with mask use and that the intention-to-treat analysis showed no difference between arms. Although our study suggests that community use of face masks is unlikely to be an effective control policy for seasonal respiratory diseases, adherent mask users had a significant reduction in the risk for clinical infection. Another recent study that examined the use of surgical masks and handwashing for the prevention of influenza transmission also found no significant difference between the intervention arms (*12*).

Our study found that only 21% of household contacts in the face mask arms reported wearing the mask often or always during the follow-up period. Adherence with treatments and preventive measures is well known to vary depending on perception of risk (*27*) and would be expected to increase during an influenza pandemic. During the height of the SARS epidemic of April and May 2003 in Hong Kong, adherence to infection control measures was high; 76% of the population wore a face mask, 65% washed their hands after relevant contact, and 78% covered their mouths when sneezing or coughing (*28*). In addition, adherence may vary depending on cultural context; Asian cultures are more accepting of mask use (*29*). Therefore, although we found that distributing masks during seasonal winter influenza outbreaks is an ineffective control measure characterized by low adherence, results indicate the potential efficacy of masks in contexts where a larger adherence may be expected, such as during a severe influenza pandemic or other emerging infection.

We estimated that, irrespective of the assumed value for the incubation period (1 or 2 days), the relative reduction in the daily risk of acquiring a respiratory infection associated with adherent mask use (P2 or surgical) was in the range of 60%–80%. Those results are consistent with those of a simpler analysis in which persons were stratified according to adherence (Technical Appendix). We emphasize that this level of risk reduction is dependent on the context, namely, adults in the household caring for a sick child after exposure to a single index case. We urge caution in extrapolating our results to school, workplace, or community contexts, or where multiple, repeated exposures may occur, such as in healthcare settings. The exact mechanism of potential clinical effectiveness of face mask use may be the prevention of inhalation of respiratory pathogens but may also be a reduction in hand-to-face contact. Our study could not determine the relative contributions of these mechanisms. In this study, it is only possible to talk about a statistical association between adherent mask use and reduction in the risk of ILI-infection. The causal link cannot be demonstrated because adherence was not randomized in the trial. Although we found no significant difference in handwashing practices between adherent and non-adherent mask users, it is possible that adherent mask use is correlated with other, unobserved variables that reduce the risk of infection. Further work will therefore be needed to definitively demonstrate that adherent mask use reduces the risk of ILI-infection.

In our study, fit testing for P2 masks was not conducted because this is unlikely to be feasible in the general community during a pandemic. As such, we felt it was more appropriate to determine the efficacy of non–fit-tested masks. We found no difference in adherence between P2 and surgical masks, an important finding, as there is a common belief among healthcare workers that P2 masks are less comfortable. The size of the study did not permit conclusive comparison of the relative efficacy of P2 masks and surgical masks. Given the 5- to 10-fold cost difference between the 2 mask types, quantifying any difference in efficacy between surgical masks and particulate respirators remains a priority that needs to be addressed by a larger trial.

A possible limitation of the study is that some adults may have been incubating infection at the time of enrollment. However, this effect would have biased the results toward the null in the intention-to-treat analysis. The survival analysis explicitly accounted for the existence of a fixed incubation period and incubating infections at the time of enrollment. A potential alternative study design would be to enroll participants from asymptomatic households, do follow-up for development of infection, and then immediately intervene with masks. For such a design, given that only 15%–20% of closely exposed adults will develop illness after exposure to an ill child, thousands of households (rather than hundreds) would be required to afford the same study power. In addition, such a design would have been fraught with underascertainment of incident infections and delayed implementation of mask intervention. We believe ours is a more efficient design. A further limitation is that some parents may have acquired infection outside the home. We identified 5 child–parent pairs with discordant viral infections. The randomization process should have ensured that outside exposure was equally distributed between arms, and this effect would have biased the results toward the null.

In retrospect, relying on laboratory-confirmed cases as the primary outcome may have been unrealistic for a study of this size. ILI in enrolled adults was 17.1%, but laboratory confirmation was modest; the virus was identified in only 34.7% of adult ILI cases (the rate of laboratory diagnosis in children was high at 63.8%). However, even intention-to-treat analysis using ILI outcome shows no significant difference between the groups. We used self-reporting to determine adherence; previous research indicates that patient self-reporting is more reliable than judgments by doctors or nurses when compared against urine drug levels (*30*). In addition, the significant association between adherence and clinical protection provides internal validation of self-reporting as a measure.

An important aspect of this study is that we included respiratory viruses other than influenza. Although these viruses may differ in their relative dependence (accurate quantitation of this relativity is uncertain for the various viruses) on different transmission mechanisms (i.e., large droplet, aerosol, or fomite), all are transmitted by the respiratory route. Therefore, face mask use should have some effect on virus transmission (e.g., interference with hand-nose contact), given that participants in all arms of the study received the same infection control advice. In addition, we argue that assessing multiple respiratory viruses allows our results to be generalized more broadly to other infections, including new respiratory viruses that may emerge in the future. Conversely, the low rate of confirmed influenza A or B infection (18.4%) in the study could mean that our findings are not directly applicable to a scenario in which influenza predominates. If influenza is more likely than the other viruses in our study to be transmitted by the respiratory route, the prevalence of mixed infections would tend to bias our results toward the null. However, it is possible that a pandemic strain may have different transmission characteristics than seasonal strains as demonstrated by attack rates in different age groups in pandemics compared with seasonal outbreaks and by the detection of influenza virus in different clinical samples in human influenza virus A (H5N1) cases.

Results of our study have global relevance to respiratory disease control planning, especially with regard to home care. During an influenza pandemic, supplies of antiviral drugs may be limited, and there will be unavoidable delays in the production of a matched pandemic vaccine (*31*). For new or emerging respiratory virus infections, no pharmaceutical interventions may be available. Even with seasonal influenza, widespread oseltamivir resistance in influenza virus A (H1N1) strains have recently been reported (*32*). Masks may therefore play an important role in reducing transmission.

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Dr MacIntyre is head of the School of Public Health and Community Medicine at the University of New South Wales, Australia, and professor of Infectious Diseases Epidemiology. Her research interests include the detailed understanding of the transmission dynamics and prevention of infectious diseases, particularly respiratory pathogens such as influenza, tuberculosis, and other vaccine-preventable infections.

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Acknowledgments

We thank John Horvath, Chief Medical Officer of Australia, for providing us with the opportunity to respond to an urgent policy need for obtaining evidence on the efficacy of using face masks. Thanks also to Noemie Ovdin, Linda Donovan, Sophie Branch, Ken McPhie, and Mala Ratnamohan for laboratory testing; Terence Campbell for comments on the manuscript; and the staff of the Emergency Department at the Children's Hospital Westmead and of the primary care practice of Michael Fasher for assisting with the recruitment of study participants.

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Figures

Figure 1. . . Flow diagram of recruitment for the prospective cluster-randomized trial, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

Figure 2. . . Compliance with mask use by day over 5 consecutive days during the study, Sydney, New South Wales, Australia, 2006 and 2007 winter influenza seasons.

Tables

Table 1. Demographic characteristics of each household by arm of randomization in the study, Sydney, New South Wales, Australia, 2006

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Follow Up

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Title: Face Mask Use and Control of Respiratory Virus Transmission in Households

CME Questions

1. Which of the following is least likely to be a nonpharmaceutical strategy examined and reported for the prevention of influenza-like infection (ILI) during an influenza pandemic?

A. School closure

B. Use of face masks

C. Handwashing

D. Quarantine at home

2. Which of the following best describes the type of study used to examine the efficacy of face masks in respiratory infection control at home?

A. Retrospective case-control study

B. Prospective cluster-randomized study

C. Prospective case-control study

D. Observational case series

3. Which of the following is the most common single viral respiratory pathogen to be isolated from 141 children with respiratory viral illness in the study reported?

A. Influenza B

B. Influenza A

C. Adenovirus

D. Respiratory syncytial virus

4. Which of the following best describes the adherence rate for P2 face masks on day 5, after beginning the use of face masks by household adult contacts for household infection control?

A. 25%

B. 31%

C. 36%

D. 46%

5. Which of the following best describes the hazard ratio for risk for transmission of ILI if adherence to face mask use was 100%?

A. 1.00

B. 0.85

C. 0.47

D. 0.26

Activity Evaluation

1. The activity supported the learning objectives.

Strongly Disagree				Strongly Agree
1	2	3	4	5

2. The material was organized clearly for learning to occur.

Strongly Disagree				Strongly Agree
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3. The content learned from this activity will impact my practice.

Strongly Disagree				Strongly Agree
1	2	3	4	5

4. The activity was presented objectively and free of commercial bias.

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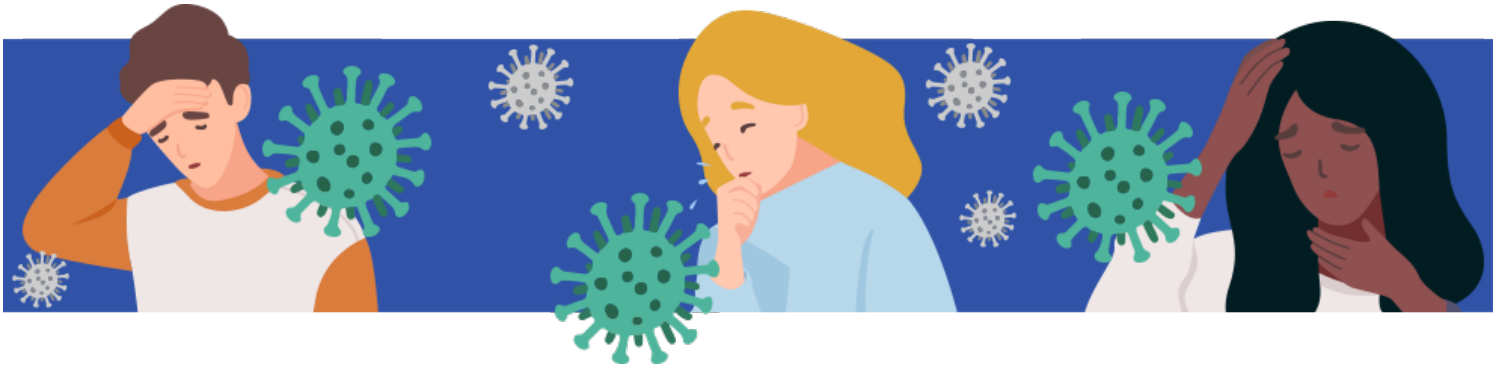
Exhibit H

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™



Similarities and Differences between Flu and COVID-19

Getting a flu vaccine during 2020-2021 is more important than ever because of the ongoing COVID-19 pandemic.

What is the difference between Influenza (Flu) and COVID-19?

Influenza (Flu) and COVID-19 are both contagious respiratory illnesses, but they are caused by different viruses. COVID-19 is caused by infection with a new coronavirus (called SARS-CoV-2), and flu is caused by infection with influenza viruses.

COVID-19 seems to spread more easily than flu and causes more serious illnesses in some people. It can also take longer before people show symptoms and people can be contagious for longer. More information about differences between flu and COVID-19 is available in the different sections below.

Because some of the symptoms of flu and COVID-19 are similar, it may be hard to tell the difference between them based on symptoms alone, and testing may be needed to help confirm a diagnosis.

While more is learned every day about COVID-19 and the virus that causes it, there is still a lot that is unknown . This page compares COVID-19 and flu, given the best available information to date.

Learn more about how to protect yourself and others from COVID-19.

Learn more about how to protect yourself and others from flu this season.

Signs and Symptoms

Similarities:

Both COVID-19 and flu can have varying degrees of signs and symptoms, ranging from no symptoms (asymptomatic) to severe symptoms. Common symptoms that COVID-19 and flu share include:

- Fever or feeling feverish/chills
- Cough
- Shortness of breath or difficulty breathing
- Fatigue (tiredness)
- Sore throat
- Runny or stuffy nose
- Muscle pain or body aches
- Headache
- Some people may have vomiting and diarrhea, though this is more common in children than adults

Differences:

Flu

Flu viruses can cause mild to severe illness, including common signs and symptoms listed above.

Flu Symptoms

COVID-19

COVID-19 seems to cause more serious illnesses in some people. Other signs and symptoms of COVID-19, different from flu, may include change in or loss of taste or smell.

COVID-19 Symptoms

How long symptoms appear after exposure and infection

Similarities:

For both COVID-19 and flu, 1 or more days can pass between a person becoming infected and when he or she starts to experience illness symptoms.

Differences:

If a person has COVID-19, it could take them longer to develop symptoms than if they had flu.

Flu

Typically, a person develops symptoms anywhere from **1 to 4 days after infection**.

Flu Symptoms

COVID-19

Typically, a person develops symptoms **5 days after being infected**, but symptoms can appear **as early as 2 days after infection** or **as late as 14 days after infection**, and the time range can vary.

COVID-19 Symptoms

How long someone can spread the virus

Similarities:

For both COVID-19 and flu, it's possible to spread the virus for at least 1 day before experiencing any symptoms.

Differences:

If a person has COVID-19, they may be contagious for a longer period of time than if they had flu.

Flu

Most people with flu are contagious for about 1 day before they show symptoms.

Older children and adults with flu appear to be most contagious during the initial 3-4 days of their illness but many remain contagious for about 7 days.

Infants and people with weakened immune systems can be contagious for even longer.

How Flu Spreads

COVID-19

How long someone can spread the virus that causes COVID-19 is still under investigation.

It's possible for people to spread the virus for about 2 days before experiencing signs or symptoms and remain contagious for at least 10 days after signs or symptoms first appeared. If someone is asymptomatic or their symptoms go away, it's possible to remain contagious for at least 10 days after testing positive for COVID-19.

How COVID-19 Spreads

How it Spreads

Similarities:

Both COVID-19 and flu can spread from person to person, between people who are in close contact with one another (within about 6 feet). Both are spread mainly by droplets made when people with the illness (COVID-19 or flu) cough, sneeze, or talk. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

It may be possible that a person can get infected by physical human contact (for example, shaking hands) or by touching a surface or object that has virus on it and then touching their own mouth, nose, or possibly their eyes.

Both flu virus and the virus that causes COVID-19 may be spread to others by people before they begin showing symptoms; by people with very mild symptoms; and by people who never developed symptoms (asymptomatic).

Differences:

While COVID-19 and flu viruses are thought to spread in similar ways, COVID-19 is more contagious among certain populations and age groups than flu. Also, COVID-19 has been observed to have more superspreading events than flu. This means the virus that causes COVID-19 can quickly and easily spread to a lot of people and result in continuous spreading among people as time progresses.

How Flu Spreads How COVID-19 Spreads

People at High-Risk for Severe Illness

Similarities:

Both COVID-19 and flu illness can result in severe illness and complications. Those at highest risk include:

- Older adults
- People with certain underlying medical conditions
- Pregnant people

Differences:

The risk of complications for healthy children is higher for flu compared to COVID-19. **However, infants and children with underlying medical conditions are at increased risk for both flu and COVID-19**.

Flu

Young children are at higher risk of severe illness from flu.

People at High Risk for Flu Complications

COVID-19

School-aged children infected with COVID-19 are at higher risk of Multisystem Inflammatory Syndrome in Children (MIS-C), a rare but severe complication of COVID-19.

People at Increased Risk of COVID-19 Severe Illness

Complications

Similarities:

Both COVID-19 and flu can result in complications, including:

- Pneumonia
- Respiratory failure
- Acute respiratory distress syndrome (fluid in the lungs)
- Sepsis
- Cardiac injury (for example, heart attacks and stroke)
- Multiple-organ failure (respiratory failure, kidney failure, shock)
- Worsening of chronic medical conditions (involving the lungs, heart, or nervous system or diabetes)
- Inflammation of the heart, brain, or muscle tissues
- Secondary bacterial infections (infections that occur in people who have already been infected with flu or COVID-19)

Differences:

Flu

Most people who get flu will recover in a few days to less than two weeks, but some people will develop complications. Some of these complications are listed above.

Flu complications

COVID-19

Additional complications associated with COVID-19 can include:

- Blood clots in the veins and arteries of the lungs, heart, legs or brain
- Multisystem Inflammatory Syndrome in Children (MIS-C)

COVID-19 Emergency warning signs

Approved Treatments

Similarities:

People at high-risk of complications or who have been hospitalized for **COVID-19 or flu** should receive supportive medical care to help relieve symptoms and complications.

Differences:

Flu

Prescription influenza antiviral drugs are FDA-approved to treat flu.

People who are hospitalized with flu or at high-risk of flu complications with flu symptoms are recommended to be treated with antiviral drugs as soon as possible.

Flu Treatment

COVID-19

The National Institutes of Health (NIH) has developed guidance on treatment of COVID-19, which will be regularly updated as new evidence on treatment options emerges.

While remdesivir is an antiviral agent that is being explored as a treatment for COVID-19 and is available under an Emergency Use Authorization (EUA), there are currently no drugs or other therapeutics approved by the Food and Drug Administration (FDA) to prevent or treat COVID-19. Studies are in progress to learn more.

What to Do If You Are Sick with COVID-19

Vaccine

Similarities:

Vaccines for **COVID-19 and flu** must be approved or authorized for emergency use (EUA) by the FDA.

Differences:

Flu

There are multiple FDA-licensed influenza vaccines produced annually to protect against the 3 or 4 flu viruses that scientists anticipate will circulate each year.

Flu Vaccines

COVID-19

Two COVID-19 vaccines have been approved for use by the FDA under an EUA. Other vaccines to prevent COVID-19 are still under development.

Prevent Getting Sick with COVID-19

Page last reviewed: January 27, 2021

Content source: Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases (NCIRD)

Exhibit I

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'Distancing isn't helping you': Indoor COVID-19 exposure risk same at 6, 60 feet, MIT researcher says

Gabrielle Masson - Friday, April 23rd, 2021 Print | Email

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People who maintain 60 feet of distance from others indoors are no more protected than if they socially distanced by 6 feet, according to a peer-reviewed study published April 27 in the *Proceedings of the National Academy of Science of the United States of America.*

Cambridge-based Massachusetts Institute of Technology professors Martin Bazant and John Bush, PhD, developed a model to calculate indoor exposure risk to COVID-19 by factoring in the amount of time spent inside, air filtration and circulation, immunization, variant strains, mask use, and respiratory activity such as breathing, eating or talking.

"We argue there really isn't much of a benefit to the six-foot rule, especially when people are wearing masks," Mr. Bazant told *CNBC*. "It really has no physical basis because the air a person is breathing while wearing a mask tends to rise and comes down elsewhere in the room so you're more exposed to the average background than you are to a person at a distance."

As with smoking, even people wearing masks can be affected by secondhand smoke that makes its way around the enclosed area and lingers. The same logic applies to airborne droplets of the virus, according to the study. However, the study did note that mask use by both infected and susceptible people reduces "respiratory plumes" and thus increases the amount of time people may safely spend together indoors.

When crafting guidelines, the CDC and World Health Organization have overlooked the amount of time spent indoors, Mr. Bazant claims.

"What our analysis continues to show is that many spaces that have been shut down in fact don't need to be," Mr. Bazant said. "Oftentimes, the space is large enough, the ventilation is good enough, the amount of time people spend together is such that those spaces can be safely operated even at full capacity, and the scientific support for reduced capacity in those spaces is really not very good."

Opening windows or installing new fans to keep air moving may be just as effective or more effective than purchasing a new filtration system, Mr. Bazant said.

The CDC currently recommends staying at least 6 feet away from other people and wearing a mask to slow the spread of COVID-19, citing the fact that the virus spreads mainly among people who are in close contact for a prolonged period.

"The distancing isn't helping you that much and it's also giving you a false sense of security, because you're as safe at six feet as you are at 60 feet if you're indoors. Everyone in that space is at roughly the same risk, actually," Mr. Bazant said.

After three rounds of peer review, Mr. Bazant says he hopes the study will influence social distancing policies.

Latest articles on infection control:

Legionella prompts evacuation of West Virginia hospital's administration building
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Minnesota nursing home gets state's largest COVID-19-related fine after employee's death

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K R • 6 days ago

Why does this seem a bit backwards? If you are at the same risk at 60 as at 6 that is not an indicator that staying 6ft apart isn't really necessary.That, instead, is evidence that indoor spaces are inherently more risky than imagined. That ,instead, suggests the airborne virus presents such risk that even at 60 it would find you... that hardly seems an argument that spaces should be opened.

"Everyone in that space is at roughly the same risk, actually,"...so if a few are shedding virus into that space then everyone is at risk even if farther than 6 feet away, no? Is now a good time to mention "Kontrol Biocloud" (an airborne virus detector from Canada)? They call it 'safe space' technology. It will tell you if the virus is present so you can move

- not 60 feet - but the hell out of the room!

4 | • Reply • Share ›

Will Goodman ↗ K R • 4 days ago

I believe the research is suggesting that indoor venues are safer than previously thought because 60 ft distancing is just as safe as 6 ft distancing. But it seems the results of this algorithm model assumes mask use.

| 2 • Reply • Share ›

James Mejuto • 5 days ago

If it's 6 -60, then, what the hell is your solution ? !

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Alan Zieve • 5 days ago

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'Distancing isn't helping you': Indoor COVID-19 exposure risk same at 6, 60 feet, MIT researcher says

Gabrielle Masson - Friday, April 23rd, 2021 Print | Email

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People who maintain 60 feet of distance from others indoors are no more protected than if they socially distanced by 6 feet, according to a peer-reviewed study published April 27 in the *Proceedings of the National Academy of Science of the United States of America.*

Cambridge-based Massachusetts Institute of Technology professors Martin Bazant and John Bush, PhD, developed a model to calculate indoor exposure risk to COVID-19 by factoring in the amount of time spent inside, air filtration and circulation, immunization, variant strains, mask use, and respiratory activity such as breathing, eating or talking.

"We argue there really isn't much of a benefit to the six-foot rule, especially when people are wearing masks," Mr. Bazant told *CNBC*. "It really has no physical basis because the air a person is breathing while wearing a mask tends to rise and comes down elsewhere in the room so you're more exposed to the average background than you are to a person at a distance."

As with smoking, even people wearing masks can be affected by secondhand smoke that makes its way around the enclosed area and lingers. The same logic applies to airborne droplets of the virus, according to the study. However, the study did note that mask use by both infected and susceptible people reduces "respiratory plumes" and thus increases the amount of time people may safely spend together indoors.

When crafting guidelines, the CDC and World Health Organization have overlooked the amount of time spent indoors, Mr. Bazant claims.

"What our analysis continues to show is that many spaces that have been shut down in fact don't need to be," Mr. Bazant said. "Oftentimes, the space is large enough, the ventilation is good enough, the amount of time people spend together is such that those spaces can be safely operated even at full capacity, and the scientific support for reduced capacity in those spaces is really not very good."

Opening windows or installing new fans to keep air moving may be just as effective or more effective than purchasing a new filtration system, Mr. Bazant said.

The CDC currently recommends staying at least 6 feet away from other people and wearing a mask to slow the spread of COVID-19, citing the fact that the virus spreads mainly among people who are in close contact for a prolonged period.

"The distancing isn't helping you that much and it's also giving you a false sense of security, because you're as safe at six feet as you are at 60 feet if you're indoors. Everyone in that space is at roughly the same risk, actually," Mr. Bazant said.

After three rounds of peer review, Mr. Bazant says he hopes the study will influence social distancing policies.

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K R • 6 days ago

Why does this seem a bit backwards? If you are at the same risk at 60 as at 6 that is not an indicator that staying 6ft apart isn't really necessary.That, instead, is evidence that indoor spaces are inherently more risky than imagined. That ,instead, suggests the airborne virus presents such risk that even at 60 it would find you... that hardly seems an argument that spaces should be opened.

"Everyone in that space is at roughly the same risk, actually,"...so if a few are shedding virus into that space then everyone is at risk even if farther than 6 feet away, no? Is now a good time to mention "Kontrol Biocloud" (an airborne virus detector from Canada)? They call it 'safe space' technology. It will tell you if the virus is present so you can move

- not 60 feet - but the hell out of the room!

4 | • Reply • Share ›

Will Goodman ↗ K R • 4 days ago

I believe the research is suggesting that indoor venues are safer than previously thought because 60 ft distancing is just as safe as 6 ft distancing. But it seems the results of this algorithm model assumes mask use.

| 2 • Reply • Share ›

James Mejuto • 5 days ago

If it's 6 -60, then, what the hell is your solution ? !

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